

## A RAND NOTE

### DESIGN OF THE PRESCRIPTION DRUG INFORMATION STUDY

David E. Kanouse, Sandra H. Berry,  
Barbara Hayes-Roth, William H. Rogers

August 1981

N-1552-FDA

Prepared For

The Food and Drug Administration



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PREFACE

The Food and Drug Administration (FDA), which is responsible for labeling prescription drugs, has promulgated regulations requiring drug information leaflets (patient package inserts or PPIs) for several major classes of prescription drugs. These leaflets, which accompany the prescription as it is dispensed to the patient, are designed to inform patients about a drug's actions, indications, and proper use, and to alert them about risks, necessary precautions, and possible side effects.

To determine how PPIs might most effectively be designed to communicate drug information, Rand has analyzed the effects of various types of PPIs through a series of experimental studies conducted with the cooperation of selected pharmacies in Los Angeles County. Patients filling prescriptions for each of three different drugs (erythromycin, conjugated estrogens, and flurazepam hydrochloride) were enlisted as experimental subjects.

This Note describes the design of the study and the rationale underlying major design choices. It describes the independent variables and how they were manipulated, the eligible subject population and experimental procedures, and the dependent and background variables and how they were measured.

The Note should be of interest to government policymakers and to members of the research and professional health care community. More broadly, it should interest all who are concerned with the use of

empirical methods to address some of the complex and controversial issues surrounding the regulation of drug information for patients.

The work reported here was supported by Contract 223-78-3009 from the U.S. Food and Drug Administration, Department of Health and Human Services. Copies of the experimental PPIs and survey instruments are appended. The Note does not describe sample selection, statistical methods, or study results; these topics are covered in the following publications:

Sandra H. Berry, David E. Kanouse, William H. Rogers, with the assistance of Jeffrey B. Garfinkle, Sample Selection for the Prescription Drug Information Study, N-1657-FDA, August 1981.

David E. Kanouse, Sandra H. Berry, Barbara Hayes-Roth, William H. Rogers, with the assistance of Jeffrey B. Garfinkle, Informing Patients About Drugs: Analysis of Alternative Designs for Estrogen Leaflets, R-2797-FDA, August 1981.

John D. Winkler, David E. Kanouse, Sandra H. Berry, Barbara Hayes-Roth, William H. Rogers, with the assistance of Jeffrey B. Garfinkle, Informing Patients About Drugs: Analysis of Alternative Designs for Erythromycin Leaflets, R-2798-FDA, August 1981.

Sandra H. Berry, David E. Kanouse, Barbara Hayes-Roth, William H. Rogers, John D. Winkler, with the assistance of Jeffrey B. Garfinkle, Informing Patients About Drugs: Analysis of Alternative Designs for Flurazepam Leaflets, R-2799-FDA, August 1981.

David E. Kanouse, Sandra H. Berry, Barbara Hayes-Roth, William H. Rogers, John D. Winkler, Informing Patients About Drugs: Summary Report on Alternative Designs for Prescription Drug Leaflets, R-2800-FDA, August 1981.

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## I. INTRODUCTION AND SUMMARY

In 1980, the Food and Drug Administration (FDA) promulgated regulations requiring manufacturers to provide, and pharmacists to dispense, informational leaflets to patients filling prescriptions for a wide variety of drugs.[1] These leaflets, which have come to be known as patient package inserts (PPIs), are designed to inform patients about a drug's actions, indications, and proper use and to provide warning information about risks, necessary precautions, and possible side effects.

Written materials have been provided to consumers of non-prescription drugs for many years, but such materials have not been required for prescription drugs until fairly recently. The first prescription labeling requirement was introduced in 1968 to warn patients that improper use of isoproterenol inhalation products could cause serious breathing difficulty.[2] Since then, prescription drug labeling has been required for several other drugs, most notably oral contraceptives and other estrogenic products.[3]

In addition to imposing PPI requirements for a few selected drugs, FDA has long been studying the possibility of requiring PPIs for a wide variety of drugs. Formal discussions with health professionals and consumer and industry groups began in 1974. The following year, several

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[1]Food and Drug Administration (1980).

[2]Food and Drug Administration (1968).

[3]Food and Drug Administration (1970; 1977).

consumer groups filed a petition with FDA to require more adequate patient labeling of prescription drugs.[4]

In response to this petition, and at the urging of its National Advisory Committee, FDA established a "Patient Prescription Drug Labeling Project" to explore the prospects and problems entailed in a general PPI requirement. FDA launched a research program and in 1976 initiated and co-sponsored a national symposium on PPIs.[5] More recently, it sponsored a national conference on PPI content and format.[6]

As a result of this program of study and research, in 1980 FDA issued regulations establishing procedures and requirements for preparation and distribution of PPIs for prescription drugs.[7] Initially, the regulations would apply to ten classes of prescription drugs,[8] with the possibility of later extensions, revisions, modifications, or curtailment based on the results of the early program. After the regulations were issued, the new administration stayed their effective date, consistent with President Reagan's executive order.[9] As of summer 1981, the FDA Commissioner was conducting a full review of the patient prescription drug labeling program to determine whether the benefits of PPIs outweigh their costs and to assess the relative

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[4]Center for Law and Social Policy, petition filed with former FDA Commissioner Schmidt, May 31, 1975.

[5]Drug Information Association et al. (1977).

[6]A. Myers (1979).

[7]Food and Drug Administration (1980).

[8]The ten drugs and classes of drugs are: ampicillin, benzodiazepines, cimetidine, clofibrate, digoxin, methoxsalen, phenytoin, propoxyphene, thiazides, and bendectin.

[9]Executive Order No. 12291, "Federal Regulation," February 17, 1981.

advantages of alternative means for delivering drug information to patients.

The research described here is the most thorough investigation conducted thus far on the effects of various prototype PPIs on actual drug users. The study was undertaken in 1978 to address an issue that has long concerned policymakers: namely, how PPIs might best be designed so as to communicate important drug information to the patient.

Drug information documents can vary radically in format, length, content, and style. Some consist of simple checklists of precautions and warnings (Fox, 1969), whereas others contain a detailed discussion of the disease with little mention of the drug itself (Sackett et al., 1975). To determine which type works best, it is desirable to conduct experiments that systematically vary such factors as the content, style, and format of the document while controlling for other factors. Few previous studies have attempted to do this. Ley, Jain, and Skilbeck (1976) found that more readable instructions led to better compliance, and Benson et al. (1977) found that women preferred longer and better illustrated brochures. However, these studies left many questions unanswered.

The research described here was undertaken to help fill the gaps in existing knowledge about how to communicate drug information to patients. Its major purpose was to determine how critical features of PPIs affect patient knowledge of the drug's purpose, actions, contraindications, and side effects. The study examines which variables enhance communication and retention of important facts about a drug.

Other outcomes are also of interest, including self-reported drug-taking behavior and reporting of side effects.

The research provides information about six different structural variables, each applied to leaflets describing three different drugs. The variables studied include specificity of instructions, amount of explanation, writing style, risk emphasis, format, and length, which are important aspects of document design. Each is in principle subject to FDA's regulatory control.

The research strategy involved providing alternative PPIs on a randomized basis to customers filling prescriptions in a sample of pharmacies. We assessed outcomes by means of a telephone interview conducted a few days after the date of the prescription and by use of a subsequent mail questionnaire. The principal emphasis was on measuring knowledge about the drug, but the study also elicited a good deal of information concerning attitudes and self-reported behavior (use of the drug, contacts with physicians, etc.). The interview obtained measures of background variables (e.g., age, education, and previous experience with the drug) that may influence outcomes independently of the effects of the PPI.

## II. DESIGN AND DESCRIPTION OF INDEPENDENT VARIABLES

The Prescription Drug Information Study examined various experimental PPIs for each of three different drugs: erythromycin, an antibiotic; flurazepam hydrochloride, a hypnotic sold under the trade name Dalmane; and conjugated estrogens, female hormones used primarily in treating vasomotor symptoms during menopause or following surgical removal of the ovaries.

The project comprised three separate studies sharing a common experimental design--a 3x2x2 factorial with three levels of drugs (a nonrandom factor) and two structural variables, each with two levels. The particular pair of variables that were combined factorially changed from study to study. In addition, each study had three control groups (one for each drug). A schematic representation of the design is shown in Table 1. Control groups for Dalmane and erythromycin did not receive a PPI. The estrogen control group received the PPI currently distributed by the manufacturer.[1]

Each of the three studies examined two different structural features of PPIs. In the first study, for example, the PPIs differed systematically in the specificity of their instructions and the amount of explanation they provided. In the second study, they varied in writing style and emphasis on risk; and in the third, they varied in length and format. Altogether, then, the studies examined six different structural features, each studied in combination with one other, which

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[1]Because the law requires PPIs for conjugated estrogen, it is not ethically (or legally) permissible to withhold this information from patients.

Table 1  
SUMMARY OF EXPERIMENTAL DESIGN

Drug	Structural Feature Combination <sup>a</sup>				Control
	A <sub>1</sub>		A <sub>2</sub>		
	B <sub>1</sub>	B <sub>2</sub>	B <sub>1</sub>	B <sub>2</sub>	
Erythromycin (R)	R <sub>11</sub>	R <sub>12</sub>	R <sub>21</sub>	R <sub>22</sub>	R <sub>0</sub>
Dalmane (D)	D <sub>11</sub>	D <sub>12</sub>	D <sub>21</sub>	D <sub>22</sub>	D <sub>0</sub>
Estrogen (S)	S <sub>11</sub>	S <sub>12</sub>	S <sub>21</sub>	S <sub>22</sub>	S <sub>0</sub> <sup>b</sup>

<sup>a</sup>Varies from study to study. For a description of the features varied in each study, see Table 2 and accompanying text.

<sup>b</sup>Control subjects for estrogen receive manufacturer's drug labeling rather than no information at all.

permitted us to examine interactions between pairs of features combined within studies.

Table 2 lists the structural features included in the design and provides a brief definition of each. The features are listed according to the study in which they appeared. For example, the first study orthogonally combined specificity of instructions with amount of explanation. Below we discuss the variables manipulated in each study and their possible effects.

#### THE BASIC PPI

To facilitate discussion of the variables, we describe a "basic" PPI, on which all other PPIs are variants. The basic PPI for each drug contained a body of "core" information--facts about the drug and

Table 2

INDEPENDENT VARIABLES: STRUCTURAL FEATURES OF PPIs

Study	Variables	Definition
1	Specificity of instructions	(Two levels) Extent to which "core facts" are elaborated with behaviorally oriented instructions on how and when to take the drug, what to do about adverse reactions, etc.
	Amount of explanation	(Two levels) Extent to which "core facts" about the drug are elaborated with explanations about why it works as it does, why certain people should not take it, why certain side effects may occur, etc.
2	Risk emphasis (tone)	(Two levels) "Risk emphasis" version highlights information about risks, precautions, dangers and side effects; "balanced" version presents the same information without special emphasis.
	Writing style	(Two levels) Simplified version versus standard version; simplified version contains fewer technical words, shorter sentences, employs active voice more frequently, and follows other rules designed to minimize reading difficulty.
3	Format	(Two levels) Text versus outline; text version presents information in full sentences and paragraphs. Outline version presents key words and phrases organized under major headings.
	Length	(Two levels) Core information versus minimal information; the minimal information version presents fewer facts (e.g., does not list as many side effects).

instructions regarding its use that the FDA considered to be fundamental. It was organized in a hierarchical, top-down fashion. The most general information appeared first; subsequent sections elaborated the general information in successively greater detail within a standard format: introduction, summary, and body.

The introduction read as follows:

[Drug] is [definition]. Like all drugs, it has both benefits and risks. You should understand both benefits and risks before deciding to take [drug]. This leaflet contains important information about [drug] and your health. Read it and save it for future reference.

The first part of the leaflet summarizes the basic facts about [drug]. Later parts of the leaflet give more detailed information about what [drug] is, why people use it, and how to use it. The last part of the leaflet tells you what precautions to take when using [drug] and what dangers and side effects might occur. If you would like additional information about [drug], contact your doctor or your pharmacist. Your pharmacist can give you a more technical leaflet to read.

The summary contained the most important points about the drug in each of the five categories listed above. They appeared in the order given in the introduction. The five categories also appeared as major section heads in the body of the PPI, again in the order given in the introduction. Under the appropriate section head, each of the points mentioned in the summary was reiterated in the context of related core information.



The basic PPIs for the three drugs, along with the variants described below, are reproduced in Appendix A.

### STUDY 1

Study 1 investigated the effects of elaborating the core information about a drug with additional information in each of two categories: explanation and specific instructions. The rationale for studying each of these variables is presented below. The methods used to manipulate them are described in a later subsection.

#### Specific Instructions

Several studies suggest that providing specific, action-oriented instructions increases acceptance of health recommendations (Leventhal, Jones, and Trembly, 1966; Leventhal, Singer, and Jones, 1965; Leventhal, Watts, and Pagano, 1967). For example, one study examined students' responses to various appeals for them to get tetanus shots. Students were more likely to comply when they were given a map depicting the location of the student health building and a suggestion that they examine their class schedules to see when they would be near the building. Because all of the students already knew where the building was, the effect was not informational.

Explicit instructions may have affected student behavior by creating an associative link between the recommendation and the cues likely to be encountered later (e.g., when students passed the health building on the way to class). Alternatively, the explicit instructions

may have produced more imagery that facilitated their recall (Paivio, 1971, 1978). Finally, explicit instructions may have increased the students' sense of personal efficacy in controlling their health outcomes (Bandura, 1977; Beck and Frankel, 1981), thereby increasing the probability that they would actually try to do so. Whatever the mechanism, it may be possible to enhance the effectiveness of PPIs by framing instructions in terms that are explicit and action-oriented, rather than vague or general.

Support for this notion is provided by a study by Bradshaw et al. (1975), who investigated recall of dietary instructions for the obese. Some subjects were given general instructions such as "You must lose weight," while others were given specific instructions, such as "You must lose seven pounds in weight." Results showed that subjects (overweight women) recalled 51 percent of the specifically worded instructions but only 16 percent of the generally worded ones. Study 1 allowed us to test whether providing specific instructions enhanced recall within a drug information document.

Providing specific rather than general instructions tends to lengthen a document, which may adversely affect consumers' willingness to read the document or their ability to remember the information. These possible negative consequences are treated more fully below.

#### Explanation

A message that includes explanations for its recommendations and warnings offers potential advantages over a message that is oriented toward unelaborated dos and don'ts. Explanation's principal advantage

is that it offers the reader not merely an isolated fact to consider and remember but also a unit of meaning surrounding that fact. Those who study how people "process" text believe that they do so by constructively interpreting meaning rather than by passively assimilating facts (Clark and Haviland, 1977; Harris and Monaco, 1978; Johnson, Bransford, and Solomon, 1973; Schank and Abelson, 1977; Thorndyke, 1977). In constructing meaning, people draw on their existing store of knowledge, actively integrating new information into established structures. Existing knowledge is often adequate to enable a person to "supply the context"--for example, to comprehend the reason lying behind a particular recommendation or warning. Sometimes, however, the reason is less obvious, and the person is forced to deal with the recommendation or warning on its own terms. This raises the danger that the person will dismiss, forget, or misconstrue the information.

An example may clarify this point. Patients taking antibiotics (e.g., erythromycin) for bacterial infections are usually told that it is important to take the full course of therapy. Very often, however, they begin to feel better after only a few days of treatment and stop taking the drug before all the bacteria have been eliminated. The bacteria that survived the first days of treatment may multiply and eventually cause a full relapse. Unless patients are told the reason that they should take all of the medicine, they may assume that the disappearance of their symptoms means that they have recovered and no longer need the medicine (Morris and Kanouse, 1979).

In general, explanation is most likely to be helpful when the reader's knowledge is sketchy or potentially misleading. In such circumstances, explanation may improve comprehension, memory, and acceptance. Explanation can make the material easier to remember by providing more retrieval routes. Moreover, recommendations that are supported by explanations may be seen as more authoritative (Morris and Kanouse, 1980) and therefore have a better chance of being persuasive.

Elaboration could also produce undesirable effects. Any elaboration, whether instructional or explanatory, increases both the amount of information in a document and its physical length. If consumers' decisions about whether to read a document are sensitive to length, the addition of explanatory or instructional material may adversely affect readership.

A large amount of information in a document may impede comprehension and memory. Many people are not very good at picking out the main points in a text (Bartlett, 1978), and poor readers are especially bad at this task (Smiley et al., 1977). People seem to learn the main points in a text better if the text does not include explanatory details (Reder and Anderson, 1980), and they can better use text-based information if the text is short enough so they can learn most of the information rather than use the text as a reference (Hayes-Roth and Walker, 1979).

The question of how much detail to require in PPIs is an important policy concern. Should PPIs be short and to the point, or should they be quite thorough in explaining how the drug works, why some people should not take it, and why certain side effects may occur? Existing

research does not satisfactorily answer this question. Survey data suggest that consumers of oral contraceptives prefer more information to less (Morris, Mazis, and Gordon, 1977). Because women on the pill are typically young and educated, however, their demographic characteristics may predispose them to views that users of other drug products might not share.

Morris et al. (1979) used focus group interviews to study consumer reactions to prototype leaflets for erythromycin. Subjects preferred medium-length documents (about 650 to 730 words) to longer and shorter versions of 1080 and 340 words, respectively. Again, however, the subjects were a fairly sophisticated group, mostly college educated. Moreover, there is no reason to suppose that consumer preferences bear any relation to effectiveness. Consumers may prefer one type of document while learning more from another.

Morris and Kanouse (1980) examined the reactions of 325 consumers, primarily college students, to the same leaflets studied by Morris et al. (1979). Length had no overall effect on subjects' scores on a knowledge test administered immediately after they had read the leaflet. Results for individual test items, however, indicated that the shortest version may have been more successful at conveying fairly simple facts, whereas the longest version may have been more successful at communicating complex information requiring integration.

Subjects in this study were also asked to rate the leaflets on a set of semantic differential items and to judge the applicability of each of a set of 20 purposes for providing such leaflets ("help you to know when to call your doctor," "get doctors off the hook legally,"

etc.). The leaflets containing explanatory materials were rated higher on a factor labeled "accuracy" (summarizing eight semantic differential items), and the leaflets that contained specific behavioral instructions were more often seen as intended to "promote good care" (a factor summarizing four items).

The effects of additional instruction and elaboration may go beyond the sheer number of facts successfully communicated, affecting a number of other, more attitudinal outcomes as well. In Study 1 we were able to examine a wide range of possible effects among a sample of actual drug users.

#### Manipulation of Variables

We manipulated each of the variables described above by systematically elaborating on the "core facts" contained in the basic PPI. The core facts consist of all statements that communicate declarative information (what the drug is, how it works, why it is prescribed, what side effects can occur, etc.). The elaborated versions contained additional explanation, additional instructions, or both. In a "low explanation" condition, only the core facts were presented; in an "explanation" condition, the core facts were elaborated to include related details, supporting information, justification, etc. The following examples from the estrogen PPI illustrate the manipulation of this variable:

##### Low explanation:

If you take estrogens while you are pregnant, it could seriously damage your child. Female children whose mothers have taken a certain kind of estrogen (diethylstilbestrol)

during pregnancy have a higher risk of getting vaginal and cervical cancer later in life.

Explanation:

If you take estrogens while you are pregnant, it could seriously damage your child. Female children whose mothers have taken a certain kind of estrogen (diethylstilbestrol) during pregnancy have a higher risk of getting vaginal and cervical cancer later in life. About four out of every 1,000 girls whose mothers take estrogens may get this kind of cancer. Many more of these girls (30-90%) may get changes in the lining of the vagina and the cervix called "vaginal adenosis." These changes could also turn into cancer.

As this example illustrates, additional explanations complement core facts. They provided more detailed information but did not alter the core facts themselves.

We manipulated the instruction variable by a similar method. The "core instructions" in the basic PPI comprised all statements suggesting the reader should take a particular action (how to take the drug, what precautions to take, what to do if certain symptoms appear, etc.). In a "no specific instructions" condition, only these core instructions were presented. In a "specific instructions" condition, the core instructions were elaborated to include more detail. The following examples from the Dalmane PPIs for Study 1 illustrate the manipulation of this variable:

No specific instructions:

If you think that you or someone else may have taken an overdose, get emergency help immediately.

Specific instructions:

If you think that you or someone else may have taken an overdose, get emergency help immediately. Call your doctor or the emergency room of the nearest hospital. Make sure that they know that the person who has overdosed has been taking Dalmane. If possible, give them the prescription container.

Again, the additional instructions complement the core instructions. They provided more detail but did not alter the core instructions.[2]

We crossed the two elaboration variables described above to produce four prototype PPIs: low explanation, no specific instructions; low explanation, specific instructions; explanation, no specific instruction; and explanation, specific instructions. Of course, the manipulations affected the lengths of the various PPIs. Table 3 shows the lengths of the Study 1 PPIs in each condition for each drug. Because the lengths of the PPIs varied, we might find an interaction between the two independent variables. It is possible, for example, that including either explanation or instruction alone could have a positive effect on memory for the information, but that including both might result in "information overload." The design of Study 1 permitted us to examine this possibility.

## STUDY 2

Study 2 investigated the effects of risk emphasis and writing style.

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[2]Wright (1979) used a similar method to study the effects of concrete action recommendations urging consumers to read package warnings for over-the-counter drugs. In his study, which varied the content of TV ads, some subjects received only a general exhortation to "read the package warnings," whereas others were given the same message with concrete descriptions of time and place: "In the store, before buying, read the package warnings."



Table 3  
NUMBER OF WORDS IN PPIs FOR STUDY 1

Condition	Drug		
	Erythromycin	Dalmane	Estrogen
Low explanation, No specific instructions	955	1175	1601
Low explanation, Specific instructions	1162	1304	1789
Explanation, No specific instructions	1192	1419	1962
Explanation, Specific instructions	1287	1536	2221

Risk Emphasis

The variable referred to as "risk emphasis" derives its importance from a long-standing controversy over what PPIs should do. One view, held most strongly by consumer groups, is that PPIs should be primarily "informed consent" documents, providing patients with the information they need to participate in decisions about their treatment. This view holds that all prescription drugs pose some risks, that consumers have the right to know about those risks, and that written information enables them to make informed decisions regarding use. (Oral communications from physicians to patients are viewed as inadequate in accomplishing this goal.) The other view holds that PPIs should be primarily patient education documents, conveying information that will

help patients know what precautions to take in using the drug, how best to take it, what effects to expect, and what to do if they experience side effects. In general, the patient education view considers increased patient responsibility to be a means rather than an end; the primary goal should be to improve patients' health outcomes by increasing their adherence to prescribed regimens.

Ultimately, FDA's policy regarding the content of PPIs will have to resolve the tension between these two views (Dwyer and Ross, 1980; Morris, 1978). The "risk emphasis" manipulation in Study 2 was intended to capture the type of design variation that might follow from FDA's adoption of one or the other of these views. The range of variation has natural limits. For example, because every PPI must contain "core facts" about a drug, completely one-sided documents stressing only a drug's risks or benefits lie beyond the pale. It is, however, quite possible to place differential emphasis on risks or benefits without much variation in actual content. The "tone" of the PPI is apt to be determined not only by the literal content but also by how the information is presented.

In Study 2, we manipulated risk emphasis with three simple stylistic devices. First, we varied the wording of an introductory statement, emphasizing either the importance of risk information or risk and benefit information. Second, we varied the order in which the information was presented--information that appears first is likely to be seen as more important (Kieras, 1980). Third, we used boldface type to highlight risk information in the "risk emphasis" PPIs. The "no risk

emphasis" PPI in Study 2 was the same as the basic PPI described for Study 1. It began with the following:

[Drug] is [drug-specific definition]. Like all drugs, it has both benefits and risks. You should understand both benefits and risks before taking [drug].

The introduction was followed by a summary of the main points covered in the PPI, followed in turn by more detailed information organized in sections: What [drug] is, How [drug] works, How to use [drug], Precautions, and Side effects. All material, except for headings, was in standard typeface.

The "risk emphasis" version differed from the "no risk emphasis" version in three ways. First the introduction read as follows:

[Drug] is [drug-specific condition]. Like all drugs, it has risks. You should understand these risks before taking [drug].

The sections following the introduction and summary were reordered as follows: Precautions, Side effects, What [drug] is, How [drug] works, How to use [drug]. The main points in the summary were also reordered in the same way. Finally, sentences describing specific risks or side effects were presented in boldface italics. Thus, the risk emphasis version presented the same information as the balanced version. Risk emphasis was manipulated solely by varying syntax and formatting conventions.

### Writing Style

Much of the existing consumer-oriented material on prescription drugs has been criticized as too difficult for many patients to

understand (Liguori, 1978; Pyrczak, 1978; Udkow et al., 1979). Our purpose in investigating this variable was to determine whether systematic efforts to simplify a PPI's text will actually improve patients' understanding. Improvement is not inevitable. Indeed, efforts to simplify a text may "turn off" many readers who find the result simplistic or patronizing. To investigate this variable, we prepared PPIs that varied in complexity. The "complex" versions consisted largely of material prepared by members of Rand's and FDA's professional staff. To produce the simplified writing style, the complex PPIs were transformed sentence by sentence according to a set of heuristics chosen on the basis of linguistic and psychological studies establishing their relationship to text comprehension.[3] Table 4 lists the heuristics used in this study and provides examples of complex sentences and their transformations. As inspection of the examples in Table 4 shows, many sentences were transformed according to more than one heuristic.

Of course, we did not transform every sentence in the PPIs. Many of the sentences produced for the standard writing version were quite simple and already conformed to the heuristics used in the study. These sentences we left unchanged. Of the remainder, we transformed only those sentences that departed radically from the prescriptions given by the heuristics. The proportion of transformed sentences differed somewhat across the three drugs. Of the 77 sentences in the erythromycin PPI, 70 (91 percent) were transformed. For the other

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[3]See Kanouse and Hayes-Roth (1980) for a discussion of the pertinent literature and of its application to the design of consumer-oriented documents.

Table 4

HEURISTICS FOR SIMPLIFIED WRITING STYLE

Heuristic	Standard Sentence	Transformed Sentence
Use the active voice.	Some important information about erythromycin and your health is provided by this leaflet.	This leaflet provides important information about erythromycin and your health.
Use imperative rather than prescriptive forms.	You should read it and save it for future reference.	Read it and save it for future reference.
Use simple vocabulary.	The hypnotic effect of Dalmane is usually felt...	Most people fall asleep...
Use informative expressions.	In the event of an overdose...	If you think that you or someone else may have taken an overdose...
Replace impersonal references with second person references.	Estrogens increase the incidence of endometrial cancer.	Taking estrogens increases your chance of getting endometrial cancer...
Avoid technical terms.	Taken this way, erythromycin can sometimes cause gastrointestinal distress.	You may get an upset stomach when you take erythromycin this way.
Replace complex subject terms with if-then constructions.	Those who are pregnant, nursing a child, or allergic to Dalmane should talk to their...	If you are allergic to Dalmane, or if you are a pregnant woman or a nursing mother, talk...
Eliminate unnecessary words.	This drug is to be administered only to the person for whom it has been prescribed.	This drug is for you only.
Include one main idea per sentence.	Dalmane can cause a number of side effects, including "hangover" effects which are sometimes experienced after waking up.	Dalmane can cause a number of side effects. Some people have "hangover" effects after they wake up.

drugs, comparable figures are 74 out of 86 sentences (86 percent) in the Dalmane PPI, and 88 out of 113 sentences (78 percent) in the estrogen PPI. The transformations had no effect on the organization of the PPI or on the ordering of sentences within paragraphs.

Application of the set of heuristics listed in Table 4 was not a mechanical process. Judgment was required to determine whether a sentence needed changing and if so, in what way. The heuristics guided such judgments, they did not replace them.[4] Use of the heuristics helped to insure that the transformations would be consistent with a specifiable set of criteria, so that the same concepts could, in principle, be tested in other studies.

Table 5 provides data on the characteristics of the resulting PPIs. Compared with the complex versions, the simplified versions contained shorter words and sentences, used fewer passive constructions and prepositional phrases, and had many more pronouns. Each of these characteristics should help make the simplified versions more readable.

In addition, the simplified versions contained many more second person references and imperative verb forms. These latter characteristics, like the others, were manipulated because of their possible relationship to text comprehension (see Table 4). However, their manipulation may also have produced important differences in the PPIs' tone. In particular, the simplified versions presented information in a more personal style aimed directly at the individual

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[4]Often many transformations were possible. Selecting among them necessarily required judgment. Moreover, the heuristics listed in Table 4 are not always consistent in practice. Replacing a technical term may "add unnecessary words" rather than eliminating them, etc.

Table 5  
CHARACTERISTICS OF COMPLEX AND SIMPLIFIED PPIs IN STUDY 2

Characteristic	Drug and Version					
	Erythromycin		Dalmane		Estrogen	
	Complex	Simplified	Complex	Simplified	Complex	Simplified
Average sentence length	13.6	12.2	14.4	13.4	16.4	15.0
Syllables per 100 words	176.5	162.7	172.9	159.3	175.2	160.0
Percent of words > 3 syllables	21.0	14.9	19.0	12.6	22.8	16.5
Percent mono-syllables	57.4	63.7	53.9	59.1	55.4	60.8
Prepositions per 100 words	10.0	8.9	9.0	7.9	10.4	8.7
Pronouns per 100 words	4.1	7.6	2.8	6.8	2.8	6.2
Second person references per 100 words <sup>a</sup>	2.2	4.7	2.7	5.8	2.0	7.0
Imperative constructions per 100 words	1.4	3.6	1.4	3.0	0.7	1.9
Passive constructions per 100 words	4.2	0.4	3.4	0.3	3.3	0.3

<sup>a</sup>Includes the pronoun "you" and the pronomial adjective "your."

reader. Also, the more frequent use of imperatives in these versions may have created an exhortative tone.

Our intent was to create versions that differed in complexity, without much variation in structure or informational content. We did not set out to capture the full range of complexity along which PPIs could in theory vary, but rather a probable range, given reasonable variations in the amount of effort devoted to simplifying these documents.

One way to gauge the success of the manipulation is to compare the complex and simplified versions on measures of readability. A wide variety of formulas are available; Table 6 shows scores for the Study 2 leaflets on five indices described by Klare (1974).[5] The complex and simplified leaflets differ as intended on all five measures and for all three drugs. Moreover, for each measure, the size of the difference between complex and simplified versions is comparable across drugs, suggesting that the strength of the manipulation is also comparable. Finally, the size of the absolute scores indicates that all of the leaflets were at least fairly difficult to read. The transformation procedure reduced the level of reading difficulty by the equivalent of two or three grades. Even the simplified versions appear to have been written at a high school level, however.[6]

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[5] These indices are all based on formulas that use one or more of the variables listed in Table 5.

[6] Some readers may wonder how the Study 2 leaflets compare in complexity with existing patient drug labeling. We applied the readability formulas listed in Table 6 to the manufacturer's leaflet for conjugated estrogens (using the leaflet provided by Ayerst for oral Premarin). On all five measures, the manufacturer's leaflet scored about midway between our simplified and complex estrogen leaflets.



Table 6  
READABILITY SCORES FOR COMPLEX AND SIMPLIFIED PPIs IN STUDY 2

Readability Index <sup>a</sup>	Drug and Version					
	Erythromycin		Dalmane		Estrogen	
	Complex	Simplified	Complex	Simplified	Complex	Simplified
Flesch Reading Ease <sup>b</sup>	43.7	56.8	45.9	58.4	42.0	56.3
Farr-Jenkins-Paterson <sup>b</sup>	46.4	57.9	40.1	49.3	40.5	50.6
Coleman four-factor <sup>b</sup>	40.1	49.9	35.8	44.3	35.9	44.7
Fog <sup>c</sup>	13.9	10.2	13.4	10.4	15.7	12.6
Smog <sup>c</sup>	12.3	10.4	12.1	10.1	13.6	11.6

<sup>a</sup>For a description of each index and its scoring, see Klare (1974).

<sup>b</sup>Higher scores indicate greater readability.

<sup>c</sup>Lower scores indicate greater readability.

The risk emphasis and writing style variables were crossed in Study 2 to produce four prototype PPIs: no risk emphasis, complex; no risk emphasis, simplified; risk emphasis, complex; and risk emphasis, simplified. It is possible that these two study variables will interact. For example, people may find the PPIs emphasizing risk to be less (or more) alarming when the writing is simplified so they can better understand the nature of the risk.[7]

### STUDY 3

Study 3 varied the amount of core information in the PPI and the mode of presentation.

#### Length

The core information for each drug covered all facts and instructions FDA considered important enough to include in a patient information document. However, we studied the desirability of abbreviating this core information first, because abbreviated PPIs might prove to be the most effective vehicle for communicating the most important points to the largest number of people. Several of the studies mentioned in our discussion of Study 1 suggest that people have difficulty identifying and learning the most important points in a text when those points are embedded in a context of more detailed information. Moreover, people might be more inclined to read a PPI if it is short.

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[7]All of the PPIs used in Studies 1 and 3 had simplified sentences transformed according to the heuristics described above. Thus, writing style was held constant in those studies.

Second, abbreviated PPIs present certain practical advantages. They may be somewhat easier to prepare, review, and revise, and possibly easier to regulate as well. The costs of printing, distributing, and storing them may also be somewhat lower.

To permit us to examine the effects of amount of information on patient outcomes, Study 3 included PPIs of varying lengths. In a "full content" condition, the PPIs contained the core information included in the basic PPI used in Study 1 and Study 2. In a "reduced content" condition, the PPIs covered only the subset of this information that FDA regarded as essential. Figure 1 illustrates the application of the reduced content variable to the basic Dalmane PPI. The portions of the text that are boxed in the figure were eliminated or greatly condensed to produce the reduced content PPI.

#### Format

In addition to the expository text format used in Studies 1 and 2, Study 3 examined the effectiveness of an outline format for presenting the same information. There are two reasons for studying this format. First, because the outline format is considerably shorter and simpler than a text format (see our discussion of length above) it may be easier for the reader to grasp the most important facts quickly. Second, the outline format may facilitate use of the PPI as a reference document. Frase and Schwartz (1979) have shown that, in a question-answering task, people can search a text more effectively if it is organized in an outline format. In part this may be because the outline format makes the structure of the document more apparent, permitting the reader to scan quickly for the desired information.

# DALMANE

(DAL-main)

flurazepam  
(floor-AZZ-a-pam)

Dalmane is used to treat insomnia. Like all drugs, it has both benefits and risks. You should understand both benefits and risks before deciding to take Dalmane. This leaflet contains important information about Dalmane and your health. Read it and save it for future reference.

The first part of this leaflet summarizes the basic facts about Dalmane. Later parts give more detailed information about the drug, how it works, how to use it, what precautions you should take when using it, and what side effects you might have. If you would like additional information about Dalmane, contact your doctor or your pharmacist. Your pharmacist can give you a more technical leaflet to read.

## SUMMARY

Dalmane is a hypnotic drug (sleeping capsule). Most people fall asleep within half an hour after taking Dalmane and remain asleep for seven or eight hours.

Take only the dose of Dalmane your doctor recommends and take it only if you need it.

Alcohol (beer, wine, whiskey, etc.) and certain other drugs may increase the effects of Dalmane. Combining any of these with Dalmane may cause you to become oversedated.

If you are allergic to Dalmane, or if you are a pregnant woman or a nursing mother, talk to your doctor before deciding to take Dalmane. Dalmane is not recommended for children, especially those under 15 years old. Do not take Dalmane if you need to be mentally alert. If you think that you or someone else may have taken an overdose, get emergency help immediately.

Dalmane can cause a number of side effects. Some people have "hangover" effects after

they wake up. If you have any side effects that bother you, check with your doctor or pharmacist.

## WHAT DALMANE IS

Dalmane is the brand name of a hypnotic drug (sleeping capsule) called flurazepam. Dalmane is a member of a class of drugs called benzodiazepines. This class of drugs also includes Valium, Librium (chlordiazepoxide), Serax, Verstram, Tranxene and Ativan.

Dalmane comes in capsules in two different strengths. The 15 milligram capsule is orange and ivory. The stronger 30 milligram capsule is red and ivory.

## HOW DALMANE WORKS

Your doctor probably prescribed Dalmane to treat insomnia (trouble sleeping).

Sometimes doctors also prescribe Dalmane for patients who are recovering from certain medical problems and require extra sleep to aid their recovery.

Dalmane usually starts working within a half hour after a person takes it and continues working for seven or eight hours. You might find that Dalmane has a stronger effect after you have taken it for a few nights.

## HOW TO USE DALMANE

Your doctor probably told you to take one Dalmane capsule at bedtime. Follow your doctor's instructions and take Dalmane only if you can't sleep. Once you have taken a capsule, do not take another one unless your doctor told you to.

You should not smoke heavily while taking Dalmane. Do not drink a lot of coffee, tea, or cola during the four hours before bedtime. If you take an antacid while you are taking Dalmane, it may take a little longer for you to fall asleep.

Do not take Dalmane for a long period of time. Take it only when you have trouble falling asleep naturally. If taking Dalmane does not help you sleep, do not increase the dosage. Tell your doctor.

Drugs similar to Dalmane can cause dependence. To avoid any possibility of dependence

(Text shown in boxes is eliminated or greatly condensed in reduced context PPI.)

Fig. 1--Example of reduced content manipulation

on Dalmane, take it only as directed and do not take it for a long time. If you have been taking Dalmane for a long time, do not stop taking it until you discuss this with your doctor.

## PRECAUTIONS

If you have had an allergic reaction to Dalmane or any related drugs (Valium, Librium, Serax, Verstram, Tranxene, and Ativan), do not take it.

Do not give Dalmane to children, especially those under the age of fifteen. Dalmane's effects on children have not been adequately studied.

Drugs similar to Dalmane cause birth defects. Dalmane might also cause birth defects.

If you are a nursing mother, Dalmane could enter your breast milk and pass to your child.

Since Dalmane will make you sleepy, do not use it when you need to be mentally alert. Do not take Dalmane when driving, using machinery, etc. Also, do not smoke in bed after taking Dalmane. In general, you should be extra careful doing even everyday tasks while you are taking Dalmane.

While you are taking Dalmane, do not drink alcohol. Check with your doctor before taking Dalmane with antihistamines (for allergies), cough and cold medicines, tranquilizers, anticonvulsants (for epilepsy), antidepressants (mood altering drugs), or narcotics (including pain killers).

Dalmane can also increase the effects of drugs used during surgery. If you plan to have surgery, including dental surgery, tell your doctor or dentist that you have been taking Dalmane.

It is possible to take an overdose of Dalmane. The symptoms of an overdose include: drowsiness, sleepiness, confusion, and coma. These are similar to the normal effects of the drug, but they are much more severe. If you think that you or someone else may have taken an overdose GET EMERGENCY HELP IMMEDIATELY.

This drug is for you only. Do not give it to anyone else. Keep Dalmane and all medication where children cannot reach them.

## SIDE EFFECTS

Side effects are unwanted effects caused by a drug. Not everyone who takes Dalmane will experience side effects. In fact, many people have none. Older people and people in a weak physical condition are more likely to have side effects. If you have any troublesome side effects, contact your doctor.

**HANGOVER EFFECTS.** You may feel dizzy, drowsy, or sluggish after waking up. You may have trouble standing, walking, or keeping your balance. Sometimes these symptoms continue throughout the day. Of course, you would expect a drug that helps you sleep to produce such symptoms. If you have any of these symptoms, sit or lie down immediately. Usually, hangover effects disappear within a few days. If the symptoms continue after the first few days, tell your doctor.

**PARADOXICAL EFFECTS.** Instead of falling asleep after taking Dalmane, some people become nervous, talkative, apprehensive, irritable or excited. They may even have hallucinations. If you have any of these reactions, stop taking the drug and tell your doctor.

**UNUSUAL SIDE EFFECTS.** A number of other side effects occur less often. These include: skin rash, headache, fever, sore throat, heartburn, nausea, vomiting, diarrhea, constipation, gastrointestinal pain, weakness, heart palpitation, yellowing of the skin or eyes, chest pains, body and joint pains, and genitourinary problems.

A number of other side effects are extremely rare. These include: sweating, flushes, blurred vision, difficulty in focusing the eyes, burning eyes, fainting, low blood pressure, shortness of breath, itching, dry mouth, bitter taste, excessive salivation, loss of appetite, euphoria, depression, slurred speech, confusion, restlessness, excitedness, or talkativeness, hallucinations, blood disorders, and elevated liver function blood tests. If you take Dalmane for a long time, it might cause some of these side effects. For this reason, your doctor may wish to perform some laboratory tests to check your liver, kidneys, and blood.

Prepared and distributed by Prescription Drug Labeling  
5600 Fishers Lane  
Rockville, Maryland 20857

November 1979

Like the text format, the outline format for Study 3 began with the introduction described above for the basic PPI. However, the summary was omitted and the main body of the text reduced to key words and phrases organized under major headings. Most of these headings were standard for all three drugs ("[Drug] is," "Uses," "How to take [drug]," "Talk to your doctor before taking [drug] if," etc.). Certain other headings are specific to the characteristics of individual drugs. For example, only the Dalmane PPI has the heading "To avoid dependency and withdrawal symptoms."

Under each heading, the main points appeared as keywords and phrases rather than as complete sentences. Figure 2 presents an example of the format variable, showing portions of the text and outline format for the (full content) Dalmane PPI. As the example illustrates, the format variable mainly affected the document's surface features without much change in informational content.

Length and format were crossed in Study 3 to produce four conditions: full content, text format; full content, outline format; reduced content, text format; and reduced content, outline format. The resulting PPIs showed marked variations in length, as Table 7 shows.

The length and format variables might interact in their effects on outcomes. For example, the outline format might be more effective for a longer PPI than for a shorter one. Study 3 permitted us to examine both the interactions and main effects associated with these variables.

## WHAT DALMANE IS

Dalmane is the brand name of a hypnotic drug (sleeping capsule) called flurazepam. Dalmane is a member of a class of drugs called benzodiazepines. This class of drugs also includes Valium, Librium (chlordiazepoxide), Serax, Verstram, Tranxene and Ativan.

Dalmane comes in capsules in two different strengths. The 15 milligram capsule is orange and ivory. The stronger 30 milligram capsule is red and ivory.

## HOW DALMANE WORKS

Your doctor probably prescribed Dalmane to treat insomnia (trouble sleeping).

Sometimes doctors also prescribe Dalmane for patients who are recovering from certain medical problems and require extra sleep to aid their recovery.

Dalmane usually starts working within a half hour after a person takes it and continues working for seven or eight hours. You might find that Dalmane has a stronger effect after you have taken it for a few nights.

## HOW TO USE DALMANE

Your doctor probably told you to take one Dalmane capsule at bedtime. Follow your doctor's instructions and take Dalmane only if you can't sleep. Once you have taken a capsule, do not take another one unless your doctor told you to.

You should not smoke heavily while taking Dalmane. Do not drink a lot of coffee, tea, or cola during the four hours before bedtime. If you take an antacid while you are taking Dalmane, it may take a little longer for you to fall asleep.

Do not take Dalmane for a long period of time. Take it only when you have trouble falling asleep naturally. If taking Dalmane does not help you sleep, do not increase the dosage. Tell your doctor.

Drugs similar to Dalmane can cause dependence. To avoid any possibility of dependence on Dalmane, take it only as directed and do not take it for a long time. If you have been taking Dalmane for a long time, do not stop taking it until you discuss this with your doctor.

## Dalmane is

- A hypnotic drug (sleeping pill)
- The brand name of flurazepam
- A member of a class of drugs including Valium, Librium (Chlordiazepoxide), Serax, Verstram, Tranxene, Ativan

## Forms available

- 15 milligram capsule (orange and ivory)
- 30 milligram capsule (red and ivory)

## Uses

- To treat insomnia
- For patients who require extra sleep to aid recovery from certain medical problems

## Effects of the drug

- Helps you sleep
- Starts working within a half hour
- Continues working for seven or eight hours
- Can have a stronger effect if taken for several nights

## Spacing of doses

- Follow doctor's instructions
- Take one capsule at bedtime
- Take only if you can't sleep
- Do not take more than one capsule unless doctor told you to

## While taking Dalmane, do not

- Smoke heavily
- Drink a lot of coffee, tea, or cola during the four hours before bedtime
- Take antacid (may take longer to fall asleep)

## To avoid dependence and withdrawal symptoms

- Take only as directed
- Do not take for long period of time
- Do not stop without consulting your doctor

Fig. 2--Examples of text and outline format

Table 7

NUMBER OF WORDS IN PPIs FOR STUDY 3

Condition	Erythromycin	Dalmane	Estrogen
Full content, Text format	955	1175	1601
Full content, Outline format	440	576	704
Reduced content, Text format	548	583	737
Reduced content, Outline format	313	382	369



### III. SUBJECTS AND PROCEDURE

#### SUBJECTS

Subjects for this study were patients filling prescriptions for any of the study drugs at any one of 69 pharmacies in the Los Angeles metropolitan area. For practical reasons, eligibility was limited to adults picking up their own prescriptions who were able to speak English.

Persons who were not picking up their own prescriptions were excluded because of the practical difficulty of obtaining informed consent. Because patients who did not pick up their own prescriptions probably differed from those who did in a number of ways (they may more often have been acutely ill or elderly), this exclusion necessarily limits the generalizability of the study results.

Juveniles were excluded for a different reason. Although it would have been possible to obtain informed consent from a parent to conduct an interview regarding a child's prescription, pilot work revealed that in such cases it is often difficult to determine who is the appropriate respondent for various portions of the telephone interview.[1]

Patients who do not speak English were excluded for obvious reasons. Although we believe that assessing the effect of, say, a

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[1]The difficulty is especially great for older children and adolescents, who assume varying degrees of responsibility for taking their medicine.

Spanish-language PPI would be worthwhile, such a project was beyond our present scope.[2]

In addition to those exclusions, we imposed certain other selection criteria specific to a particular drug. For estrogens, the study was restricted to women[3] and limited to tablet forms of the drug (the study excluded women using estrogen creams or taking estrogen by injection). The study also excluded nontablet forms of erythromycin (e.g., liquid preparations and suppositories). Alternative forms of delivery were excluded for these drugs both because the PPI directions were oriented toward tablet forms and because allowing for alternative forms of delivery would introduce additional complications into the telephone interview.

Subject to the above exclusions, all patients filling prescriptions for the three study drugs were eligible to participate in the study. Not all those who were eligible to participate actually did so, however. Participants were necessarily limited to the subset of patients who were asked to participate by the pharmacist, who agreed to do so, and who actually completed a telephone interview. Refusals and contact failures had the potential to limit the representativeness of the sample. We used a variety of techniques for assessing the potential biases introduced by such selection factors; these are described in detail in Berry, Kanouse, and Rogers (1981).

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[2]Spanish-language PPIs have been included in studies by Kanouse and Morris (1978) and Mansbridge (1980).

[3]Very few men take estrogens; those who do (e.g., transsexuals and cancer patients) are not likely to find either the PPI or the telephone interview applicable to their circumstances.

Our ability to generalize from the results of this study depends in large measure on the characteristics of the patients recruited as subjects, which turn are heavily dependent on the characteristics of the pharmacies from which they were drawn. For example, if the pharmacies in the sample were primarily located in upper income, suburban shopping centers, we would have little confidence in the applicability of the findings to less educated respondents living in working class neighborhoods.

We devoted special attention to ensuring that our sample of pharmacies was chosen so that the resulting sample of subjects represented a wide range of ethnic, socioeconomic, and educational backgrounds, and also a variety of pharmacy or treatment settings. We used a generalized stratified sampling algorithm known as the finite selection model (FSM). Strict random sampling of the population of pharmacies or patients was not a goal of this sampling strategy. Rather, we wished to select pharmacies so as to facilitate observing any true effects associated with the type of pharmacy and the characteristics of its clientele. The FSM (C. Morris, 1979) is both a set of concepts and a computer package designed to draw representative samples that do not confound the variables of interest.

Our procedure involved the following steps. First, we identified the population of all pharmacies in Los Angeles County, using a list provided by the California State Department of Consumer Affairs. Second, we located each pharmacy on a map and drew a circle around it to identify the area within one-half mile of the pharmacy. Third, we used 1970 Census data to identify the demographic characteristics of this

surrounding area. Pharmacies in the county were identified by type (chain or independent) and their average neighborhood characteristics were entered on the computer. Pharmacies serving heavily Spanish-speaking neighborhoods were eliminated from sample eligibility, as were certain special types of pharmacies (e.g., nonretail and homeopathic pharmacies). The FSM was then applied to select a set of pharmacies offering an optimal mix of demographic and other characteristics. Suitable replacements for each pharmacy were also identified to allow for initial refusals and later attrition. A detailed description of the pharmacy selection procedure and its results are presented in Berry, Kanouse, and Rogers (1981).

#### PROCEDURE

The pharmacist approached eligible customers when they presented or picked up their prescriptions. Customers were told that the pharmacy was cooperating with The Rand Corporation in a study of "the information people have about prescription drugs." The pharmacist handed the customer a brochure entitled "Questions and Answers About the Prescription Drug Information Study," which the customer could read while waiting for the prescription to be filled. This brochure briefly explained the study's purpose and what would be asked of participants. Customers who agreed to participate were then asked to read and sign an authorization form giving the pharmacist permission to release information about the prescription to Rand. The form explained that the study was voluntary, outlined the procedure that would be used to contact the customer for an interview, and emphasized the

confidentiality of the data and the customer's freedom to withdraw from the study at any time.

The pharmacist gave each customer who agreed to participate a PPI that was preselected according to a random schedule. We provided pharmacists with detailed instructions on how to solicit client participation and how to deliver the experimental PPI. These instructions, described in Berry, Kanouse, and Rogers (1981), were designed to ensure that the solicitation would not interfere with the pharmacist-client relationship (e.g., clients were not to be pressured into participating) and that clients would be given only enough information to permit them to make an informed choice about participating. The purpose of the latter part of this strategy was to minimize the possible sensitizing effects of the informed consent procedure.[4]

We picked up signed authorization forms from each pharmacy once a week, along with information concerning enrollees' prescriptions. This information included the brand name of the drug, dosage and regimen, and number of tablets dispensed, and it was checked against eligibility criteria before we called respondents for an interview.

We called eligible respondents for a telephone interview an average of two to three weeks after the date of the prescription.[5] We

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[4] Naturally, we could only reduce rather than entirely eliminate the sensitizing effects of the informed consent procedure. Subjects who have just agreed to participate in a drug information study who then find a drug information leaflet in their prescription package may respond somewhat differently to the leaflet as a result of their participation in the study.

[5] Erythromycin participants were called as soon as possible after the prescription date. For estrogen and Dalmane participants, cases were held a minimum of ten days in order to give the participant time to gain experience with the drug before the interview. For all three

attempted to complete the interview on the first call whenever possible but called back a minimum of six times if the respondent was difficult to reach. The telephone interview, which took approximately 45 minutes to complete, covered a variety of topics, including drug knowledge, self-reported drug taking behavior, clinical course, reporting of side effects, and reactions to the PPI (see Sec. IV). At the end of the telephone interview, respondents were asked to provide an address so that their participation payment could be sent to them.[6] They were also asked whether they would be willing to fill out a supplementary questionnaire to be returned by mail. Those who agreed to do so were sent, along with their payment, a questionnaire containing certain attitude measures and rating scales that were difficult to administer by telephone.

Approximately 15 percent of the sample was randomly selected to participate in a brief telephone validation survey, whose main purpose was to maintain quality control (e.g., to be sure that an interview was actually conducted); however, the survey also validated the PPI manipulations. Respondents who reported that they still had the PPI were asked to bring it to the telephone and read off certain code numbers, which we checked against study records obtained from the pharmacy. This procedure permitted us to determine the accuracy of the random assignment and recordkeeping procedures.

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drugs, the length of time actually required to complete the interview varied depending on how long it took to reach the respondent.

[6]Each respondent was paid \$2.50 for participating in the telephone survey.

To sum up, data were obtained from a number of sources. Information about each prescription was obtained from the pharmacy, which recorded the details necessary to compare actual and prescribed drug use. The telephone survey was the principal source of information about the characteristics of the respondent and about the outcome variables that are of primary interest. The mail follow-up questionnaire provided supplementary information on other, largely attitudinal, outcomes. The validation survey provided information on the integrity of the manipulation.

We asked pharmacists to report all cases in which a prescription was brought back for a cash refund, so that we could assess whether PPIs encouraged the return of unused prescriptions, as some have claimed.[7]

#### THE CONSUMER SURVEY

To obtain additional information on responses to the study PPIs, we conducted a supplementary survey of a convenience sample of 960 men and women. Subjects for this "consumer survey" were volunteers from various community organizations--church groups, civic groups, charitable organizations, and the like. As much as possible, they were chosen to be demographically similar to our sample of actual drug users.

Consumer subjects were surveyed in groups of 3 to 55; the average group size was 21. Each subject was randomly assigned to receive one of the study PPIs and read it carefully. Subjects were then given a

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[7]For example, the American Pharmaceutical Association (Apple, 1981) estimated that for every 60 new prescriptions, PPIs will cause one additional prescription to be returned. The cost of returned prescriptions would be borne by the pharmacy, which would pass it on to the consumer in the form of higher drug prices.

questionnaire containing items that measured comprehension of the material in the PPI and soliciting their subjective reactions. These reactions, obtained immediately after subjects had read the PPI, provide useful information on how the PPI was perceived--information that is not available in the telephone survey.[8]

Consumer subjects did not receive individual compensation for their study participation. However, each cooperating group received a payment of \$1.00 for each study participant it supplied. The survey sessions, which took about an hour to complete, were usually conducted during or immediately after a regularly scheduled group meeting.

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[8] Consumers were asked to rate the PPI on a set of 16 semantic differential scales and to rate the applicability of each of a set of 21 possible reasons for providing the PPI. These portions of the consumer survey questionnaire are reproduced in Appendix G. Other portions of the questionnaire were adapted with only minor format changes from the telephone and mail survey instruments and are therefore not shown.



#### IV. BACKGROUND VARIABLES

Each of the variables and operational measures in the study can be classified into one of three categories:

- o Independent (experimental) variables
- o Background variables
- o Dependent variables

Independent variables are those under direct experimental control and include presence or absence of a PPI and its experimentally manipulated characteristics. Background variables are those that are not under direct experimental control but that might nonetheless play a role in influencing outcomes. In this study, background variables include the subject's demographic characteristics and previous experience with the drug.

Dependent variables include all variables whose status we wish to measure as outcomes of the experimental treatments. The principal dependent measures in this study are patient knowledge, attitudes, and behavior. However, in the categorization presented here, we have also classified as "dependent" variables some measures, such as attitude toward medication, that might also be considered background variables.[1] This section and the one that follows describe the major

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[1]Because the telephone survey was conducted after the experimental intervention, premeasures are not available. Accordingly, we have been quite conservative in classifying variables as background rather than dependent variables. Background variables are those that, although measured retrospectively, are unlikely to have been affected by the experimental intervention. All others are potential dependent variables.

categories of variables measured in the study and discuss the reasons for their selection and the methodological considerations that underlie the choice of specific measures. Our goal is to describe the data collected rather than the variables actually used in analysis. For that reason, we do not report the results of methodological analyses, nor do we describe the scales and summary measures constructed as a result of these analyses. Those topics are treated in our analytic reports.[2] Here we describe study measures according to the apriori categories used in their selection.

Table 8 lists the major background variables. The variables are organized by unifying concept (shown in the column on the left), and descriptions of specific variables are shown in the middle column. The column on the right indicates how each variable was operationalized by referring to specific item numbers in the telephone survey instrument for each drug (see Appendixes B, C, and D).

#### PATIENT DEMOGRAPHIC CHARACTERISTICS

These variables are important for two reasons: First, they may predict patient knowledge, attitudes, and behavior in their own right, independently of the effects of the experimental interventions; second, they may make it easier to compare results with those of other studies and to extrapolate the findings to different populations whose demographic characteristics are known.

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[2]See Berry et al. (1981), Kanouse et al. (1981), and Winkler et al. (1981).

Table 8  
BACKGROUND VARIABLES

Conceptual Category	Specific Variables	Telephone Survey Instrument Item Number		
		Erythromycin	Dalmane	Estrogens
Patient demographic	Age	99	110	128
	Sex	96	107	125
	Race/ethnic group	107	118	136
	Marital status	97	108	126
	Occupation	102-106	113-117	131-135
	Education	100,101	111,112	129,130
Previous experience with drug	New prescription	7	7	7
	Number of times used in past year	47,48	50,51	15,16,63
	Experience with similar drugs in past	(a)	54,55	55,56
	Adverse reactions in past	49	52,56	(a)
Nature of symptoms	Type of indication	31,32,36	37,38	34-36
Previous experience with symptoms	Length of time with symptoms	(a)	(a)	65-68
	Length of time experi- enced in past year	45	48	(a)
Provider character- istics	Type of treatment setting	51,53	60,62	72,74
	Type of pharmacy	(b)	(b)	(b)
Verbal facility	Word definition, medical terms	95	106	124
Previous contact with PPI	Whether received PPI before	(a)	(a)	60
	Whether read PPI before	(a)	(a)	61
	Length of time since reading PPI	(a)	(a)	62

<sup>a</sup>Not asked for this drug.

<sup>b</sup>Information available from study records.

The list includes some of the most commonly used demographic variables but does not include the respondent's income. To provide an index of socioeconomic status, the survey elicits information about occupation, a less sensitive topic.

#### PREVIOUS EXPERIENCE WITH DRUG OR SYMPTOMS

Familiarity with the drug or the symptoms is apt to be associated with having more knowledge about them and is therefore likely to be a useful control variable. Long experience with the set of symptoms or the drug may reduce the probability that the individual will read a PPI or change his or her behavior to conform with its instructions. One study suggests that familiarity with a health threat tends to increase the individual's sense of vulnerability to that threat (Leventhal et al., 1960). Other studies, however, suggest that experience with symptoms reduces the individual's proclivity to seek care (Banks and Keller, 1971; Safer et al., 1979). Either way, experience may shape the individual's reaction to written drug information.

#### PROVIDER CHARACTERISTICS

Different treatment settings may provide patients with differing amounts of information. Professionals working in crowded outpatient clinics may not have as much time to devote to information-giving as many private practitioners do. Patients treated in such settings may, on the average, be more in need of written drug information to supplement the oral instructions of the provider. Whether this is so, and whether such patients are more or less likely to read such information is an important--and empirical--question.

The type of pharmacy where the medication and PPI are dispensed may also prove important. Several types of pharmacies served as data collection sites in the present study, including chain, independent, and medical center pharmacies. The design of the study permits a partitioning of the outcome variance associated with pharmacies into two parts: one associated with patient characteristics and one associated with pharmacies themselves. Such an analysis would indicate the magnitude of the effects associated with the information-giving milieu.

#### VERBAL FACILITY

Previous research suggests that patients' verbal facility in general and their familiarity with medical concepts in particular may affect their ability to absorb and retain new medical information. Ley and Spelman (1965) found that those with the greatest medical knowledge remembered the most new information, even when intelligence was controlled for. More generally, a study by Miyake and Norman (1979) suggested that people may become more actively engaged in reading a text if its level of difficulty matches their knowledge. In that study, novice learners asked more questions than trained learners when the material was easy, but the reverse was true for difficult material.

The questionnaire for this study included a set of "word definition" items designed to provide a measure of subjects' medical knowledge and their facility with the manipulation of verbal symbols. The measure required the interviewer to take down verbatim responses, which were then coded for accuracy.

PREVIOUS CONTACT WITH PPI

Most subjects who had been taking estrogen before entering the study probably received a manufacturer's PPI, and many had probably read it at one time or another. Whether and how recently they had done so could affect the level of knowledge they brought to their reading of the experimental PPI.

## V. DEPENDENT VARIABLES

Tables 9 and 10 list the dependent variables included in the study. Measures for most of these are based on similar measures used in previous research. For example, knowledge questions and questions about side effects draw on similar items in a previous study of leaflets for thiazide drugs (Kanouse and Morris, 1978). Attitude and individual difference measures have been selected primarily from the existing health measurement literature and adapted to the needs of the present study.

### KNOWLEDGE ABOUT THE DRUG

Communicating important drug information to the patient is the principal goal of PPIs. Written drug information has formed a part of several successful educational interventions aimed at increasing knowledge of drug therapy (Bentz and Deliganis, 1974; Deberry, Jeffries, and Light, 1975; Ellis et al., 1979; Madden, 1973; McKenney et al., 1973; Rosenberg, 1971; Sackett et al., 1975). We expect that PPIs will increase patient knowledge in this study as well. Our main interest here is in measuring the relative gains in knowledge produced by different versions of a PPI.

Our approach uses both open-ended "recall" measure (to measure knowledge of side effects) and forced choice "recognition" measures (to measure other types of drug knowledge). The forced choice knowledge measures, like measures of other constructs discussed below, rely on a multi-item rather than single-item approach. This increases the

Table 9

DEPENDENT VARIABLES: TELEPHONE SURVEY INSTRUMENTS

Conceptual Category	Specific Variables	Telephone Survey Instrument Item Number		
		Erythromycin	Dalmane	Estrogens
Knowledge about the drug	Name and type of drug	1,6	1,6	1,6
	Indications and actions	64,65	16	87,88,89
	Contraindications	66	71	90
	Proper use	13,14,16, 23-25,62	(a)	(a)
	Side effects	68	74,75,76	94,95,97
	Special precautions	26	36,72	91,92
	Other drug knowledge	(a)	13,28	85,86
Drug-taking behavior	Number of tablets taken since prescription	8,27	8,23	8,23
	Doses missed or taken late	59-61	(a)	80-82
	Appropriate usage, self-rated	(a)	68,69	(a)
	Decisions regarding drug	8-10,28	8-10,24	8-10,
	Other drug usage	(a)	14,17,18, 20,21	13,17-20
Self-rated clinical course	Change in status of symptoms	35	40	39
	Change in overall health	38	41	40
Occurrence of side effects	Possible drug reactions experienced	41A	44A	43A
	Non-drug reactions experienced	41A	44A	43A
Attribution of side effects to medication	Attribution of possible drug reactions to drug	41B	44B	43B
	Attribution of non-drug reactions to drug	41B	44B	43B
Attitudes toward drug	Perceived effectiveness	37,63,90	70,100	83,119
	Perceived safety	43,44,67	46,47, 73,77	45-50,93
	Intentions regarding future use	28,29,92	24-26, 102-103,	24-26,121
	Overall satisfaction	93,94	104,105	122,123
Attitudes toward symptoms	Perceived seriousness	91	101	120
	Amount of discomfort	89	98,99	118



Table 9 (cont.)

Conceptual Category	Specific Variables	Telephone Survey Instrument Item Number		
		Erythromycin	Dalmane	Estrogens
Contacts with providers	Information initially provided by physician	17,19,20, 39,40	19,22,32, 33,42,43	14A,22A 28-31, 41,42
	Later contacts with physician	54,55	63,64	75,76
	Satisfaction with information provided by physician	21	34	32
	Information initially provided by pharmacist	18	30,31	14B,22B
	Later contacts with pharmacist	56,57	65,66	77,78
Other sources of information	Relatives or friends taking drug	(a)	57	69
	Discussed drug with relatives or friends	(a)	58	70
	Heard TV or radio news about drug	(a)	(a)	51
	Read about drug in newspapers or magazines	(a)	(a)	53
Perceived social support for taking drug	Friends, relatives, news media	(a)	59	52,54,71
Reactions to PPI	Noticed leaflet	69-70	78-79	98-99
	Read leaflet before starting medication	71	80	100
	Read leaflet later	72	81	101
	Referred to leaflet again	73,74	82,83	102,103
	Kept leaflet	75-78	84-87	104-107
	Showed leaflet to someone else	79,80	88,89	108,109
	Novelty of information	81	90	110
	Readability	82,83	91,92	111,112
	Emotional effect	84,85	93,94	113,114
	Usefulness	86,87	95,96	115,116

<sup>a</sup>Not asked for this drug.

Table 10

DEPENDENT VARIABLES: MAIL SURVEY INSTRUMENTS

Conceptual Category	Specific Variables	Item Numbers <sup>a</sup>
Individual difference measures		Part II
	Attitude toward medication	5,6,12,17,24,30,37,39
	Health locus of control:	
	Self-care	1,20,27,35
	Provider care	11,18,23,38
	Chance	14,25
	Difficult world	7,33
	Desire for information-giving and responsibility	3,9,16,19,22,26,31,40
	Perceptions of doctor information-giving	2,15,21,32,36,42
	Doctor thoroughness	10,28
General health ratings	Attitude toward medical risk/risk explanation	4,13,34,41
	Perceived medical consensus regarding treatment	8,29
		Part III
	Current health	1,7
	Prior health	2
	Health outlook	3
	Health worry/concern	4
	Rejection of sick role	5
	Resistance/susceptibility to illness	6
		Part IV
Attitude toward medication decision	Semantic differential ratings	

<sup>a</sup>Item numbers are the same across drugs.

reliability of the overall knowledge score by sampling a greater number of categories in the underlying construct. By examining the intercorrelations among items, it is possible to assess the reliability of the measures while identifying and eliminating from further analysis items that do not measure the construct.

Whenever possible, we constructed the forced choice items so as to control for certain types of systematic guessing or response bias. We were especially concerned with controlling for biases that might be affected by reading the PPI, independent of any gain in actual knowledge. For example, some of the forced choice questions asked respondents about specific risks associated with use of the drug. We were concerned that some respondents who read the leaflet might acquire only a general impression that the drug was risky, with little or no knowledge of specific risks. If so, such respondents might be inclined to answer any forced choice item in the affirmative (e.g., "Would there be any special problem taking erythromycin for someone who has liver trouble?" "Yes." "For someone who is allergic to penicillin?" "Yes."). To distinguish gains in knowledge from shifts in attitudes, it is necessary to control for this kind of response bias. We attempted to do this by balancing our forced choice items for direction of scoring. For example, questions about specific risks whose correct answer was "yes" were balanced with questions about equally specific nonrisks whose correct answer was "no," or (when the information was not covered in the PPI) "don't know." This strategy removed much of the potentially confounding effect of response bias from our knowledge measures.

#### DRUG-TAKING BEHAVIOR

We obtained several measures of drug-taking behavior, all based on respondent self-report. Respondents were asked whether they had taken any tablets or capsules from their prescription yet, and if not, why not. Erythromycin and Dalmane respondents who had begun taking tablets were asked to estimate how many times they had missed a dose or taken one late. Respondents for all three drugs were asked to locate the container and count the remaining tablets or capsules. The number remaining was subtracted from the number dispensed (obtained from pharmacy records) to determine the number taken. For estrogen and erythromycin respondents, this number was then compared with the number the respondent should have taken under the prescribed regimen (also obtained from pharmacy records, or where missing, from the respondent).

Lack of compliance is an especially serious problem in antimicrobial therapies (Marston, 1970; Sackett, 1976), and there is evidence that written drug information can sometimes improve compliance with this type of therapy (Lima et al., 1976; Linkewich, Catalano, and Flack, 1974; Mattar, Markello, and Yaffe, 1975; Sharpe and Mikeal, 1974). Use of written drug information to improve compliance with long-term therapy has generally been less successful (Hecht, 1974; Ley, Jain, and Skilbeck, 1976; McKenney et al., 1973; Sackett et al., 1975). In the present study, we expected that the PPI's explanation of why it is important to complete a prescribed erythromycin treatment program might improve compliance by dissuading some patients from discontinuing therapy as soon as they begin feeling better (Morris and Kanouse, 1979).

Little is known about how various types of written information influence the way patients take prescription medicines for such chronic problems as insomnia.[1] By comparing the frequency with which Dalmane users take their medicine across experimental conditions, we could gauge whether the leaflet made subjects more conservative or more liberal in their use of the drug. We were also able to link any differences in usage patterns to critical features in the document.

To provide an additional perspective on the drug usage of Dalmane patients, the survey inquired about the appropriateness of drug use. Patients were asked whether there were any times that they should have taken the drug and didn't, and whether there were any times they took the drug when they probably didn't have to. Respondents providing affirmative answers to either of these questions were asked to estimate the number of times the event occurred.

#### SELF-RATED CLINICAL COURSE

The study provided for measures of the patient's own assessment regarding changes in the symptoms for which treatment was prescribed. For two of the drugs (erythromycin and estrogen) these symptoms can differ considerably from patient to patient. To provide a common basis on which to compare patients, we obtained estimates of improvement or worsening in the symptoms taken as a whole, and of changes in overall health.

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[1]Despite the continuing scientific ignorance on this matter, the Institute of Medicine recently concluded that "patients should receive clear directions and warnings about the use of hypnotic drugs." (Institute of Medicine, 1979a, p. 138.) The Institute explicitly recommends the use of informational brochures in addition to oral instructions.

#### OCCURRENCE AND ATTRIBUTION OF SIDE EFFECTS

A major concern in considering what to tell patients about possible side effects is that patients' knowledge of such effects could produce them through suggestion (Carlova, 1974). It has long been known that even pharmacologically inert substances (placebos) can induce the reporting of side effects (Brown, 1948; Diehl, 1933; Feather, Chapman, and Fisher, 1972; Pogge, 1963); however, the process by which this occurs is not understood. The belief that one has taken a drug may influence the reported frequency of such reactions, or merely the probability that they will be labeled as side effects.

Unfortunately, previous studies of the effects of forewarning patients about side effects (Myers and Calvert, 1973, 1976, 1978) do not permit one to disentangle frequency of labeling from frequency of reporting. Moreover, recent evidence suggests that this distinction is important, and that failure to make it can cloud one's ability to interpret results (Morris and Kanouse, in press). The present study provided measures that help preserve this distinction. Patients were first asked to report on the occurrence or nonoccurrence of each of a number of symptoms, some of which could be real side effects of the drug and some of which could not. (Inclusion of nondrug reactions permits some degree of control for response sets and individual differences in perceived symptomatology apart from the drug.) For each symptom the respondent reported having experienced since the date of the prescription, the respondent was asked whether he or she thought the problem was related to the drug. This method permits separation of the reported occurrence of possible drug reactions from the reported frequency of reactions which the patient labels as side effects.

#### ATTITUDES TOWARD DRUG AND SYMPTOMS

The health belief model (Becker, 1974; Rosenstock, 1966, 1974) suggests that patients' health care behavior is related to their beliefs about both a disease and its treatment. Specifically, the probability that they will undertake and follow through with a given therapy should be a function of their belief about the seriousness of the disease, the consequences of failure to treat it, and the efficacy and safety of therapy. The variables in the health belief model have been fairly successful in predicting both illness behavior and compliance with prescribed regimens (Becker et al., 1977; Kasl, 1974; Kasl and Cobb, 1966; Kirscht, 1974; Sackett and Haynes, 1976). Measures of the major constructs in the model were included in the interview protocol. In addition, for estrogen therapy, we constructed separate measures for the perceived risks of short-term vs. long-term use. For this drug, we also distinguished between side effects that may cause discomfort or annoyance (such as breast tenderness and weight gain) from those that constitute serious long-term health risks (e.g., endometrial cancer).

#### CONTACTS WITH PROVIDERS

Members of the medical community have expressed concern that PPIs might affect the amount of contact between patients and health care providers. Two contrasting fears have been voiced: The first is that PPIs will decrease patients' reliance on their physicians, thereby interfering with the provision of physician services (Gross, 1978) and

perhaps leading patients to venture into the possibly treacherous territory of self-diagnosis, self-monitoring, and self-care (Carlova, 1974; Demkovitch, 1979; Vincent, 1977). The contrasting fear is that PPIs will increase patients' demands for provider time, thereby increasing the costs of health care. For example, PPIs may lead patients to make repeated calls to their physicians to report on the status of their most recent side effects, or to seek reassurance that nothing untoward will happen to them (Carlova, 1974).

Previous research offers little evidence on whether either of these effects occurs. The only relevant data come from Morris, Mazis, and Gordon (1977), who asked oral contraceptive users whether the PPI increased or decreased the frequency of their contacts with physicians. About three-quarters said that it had no effect, and 9 percent did not answer or said that they did not know. Among those who reported a change, the change was more often in the direction of decreased contact (10 percent) rather than increased contact (5 percent).

There is theoretical reason, however, to expect that patients who receive written information about their drug may engage in more information-seeking. For example, Skipper, Tagliacozzo, and Mauksch (1964) have suggested that one of the reasons patients typically fail to ask questions about their therapy or volunteer pertinent information to their physicians is that physicians do not volunteer much information to them. A patient may not report the occurrence of a new symptom because the patient cannot evaluate its importance. PPIs may help to give the patient a framework, however sketchy, within which to decide what is worth discussing with the physician and what is not.



Second, the PPI may provide a set of concepts and terms that the patient can draw on in framing questions. Roter (1977) found that it was possible to increase the number of questions patients asked by providing a structure within which they could identify questions they had (e.g., "What do I do if I miss a dose?") and rehearse ways of asking them. Roter found that this intervention led to greater feelings of personal control, improved health outcomes, and better medical appointment-keeping. It also led, however, to increased hostility toward physicians and less satisfaction with medical care. The latter finding may reflect difficulties on the part of physicians and patients in adjusting to a new type of relationship. Physicians are as unaccustomed to being questioned as patients are to questioning (Boreham and Gibson, 1978; Pratt, Seligman, and Reader, 1957; Reader, Pratt, and Mudd, 1957; Skipper, Tagliacozzo, and Mauksch, 1964; Tagliacozzo and Mauksch, 1972). A change in patients' informational demands may well put a strain on the relationship.

#### OTHER SOURCES OF INFORMATION

PPIs may sensitize patients to other sources of information about the drug they are taking or stimulate them to discuss the drug with family or friends. If so, then PPIs may produce indirect effects on patients' knowledge, attitudes, or behavior that depend on contacts with other sources.

For two of the study drugs, we gathered information on respondents' exposure to a variety of information sources. We asked both Dalmane and estrogen respondents whether they knew any friends or relatives who were

taking the drug, and whether they had discussed taking the drug with any of their friends or relatives. In addition, we asked estrogen respondents whether they remembered having heard anything about estrogen on television or radio and whether they remembered reading anything about estrogen in a newspaper or magazine.[2]

#### PERCEIVED SOCIAL SUPPORT FOR TAKING THE DRUG

A number of researchers have suggested that the family has an important influence on health and illness behavior (Litman, 1974; McEwan, 1974; Twaddle, 1969). Oakes et al. (1970) found that compliance with a splint-wearing regimen was greatest among patients who believed that their family expected them to wear the splint. And Osterweis, Bush, and Zuckerman (1979) found that the individual's use of medicines is strongly related to the level of medicine use by other family members, suggesting that intra-family influence processes may be at work.[3]

It is likely that the support or opposition of family members--and possibly friends as well--has an important bearing on the individual's decisions regarding drug therapy. Among women taking estrogen for menopausal symptoms, for example, it is not difficult to imagine that a husband's views regarding the risks or benefits of treatment may

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[2] Stories about the risks of estrogen therapy have appeared in the media several times over the past few years; many estrogen respondents have undoubtedly encountered such publicity. News stories and magazine features also appeared during the time we were fielding this study. However, we made no attempt to ask respondents about which stories they had encountered.

[3] Some of the relationship between individual and family use of medicines is probably accounted for by shared morbidity.

sometimes carry as much weight as the patient's own views. Accordingly, for Dalmane and estrogen, we have included questions about perceived support or opposition by friends and relatives to the patient's use of the drug. Because the PPI might lead patients to discuss the drug with friends and family members, we have classified this as a dependent variable.

#### REACTIONS TO THE PPI

Because the PPI contains warnings about who should not take the drug, it is important to learn how many patients read the document before beginning drug therapy. Accordingly, we asked respondents whether they read the PPI, and if so, when. We also asked whether they kept the PPI, whether they referred to it later, and whether they showed it to anyone else. Showing the document to others may indicate that the patient regards the information as important, and may also tend to accompany the seeking of advice or encouragement from others. We also asked respondents whether they found the PPI easy or hard to read, whether they found it useful, and whether they found any of the information it contained to be novel or upsetting.

#### GENERAL HEALTH RATINGS

The mail follow-up questionnaire included seven items designed to measure respondents' perceptions of their general health. The items were adapted from a larger set used in Rand's Health Insurance Study (Ware, Davies-Avery, and Donald, 1978). They included measures of Current Health, Prior Health, Health Outlook, Resistance-Susceptibility

to Illness, Health Worry/Concern, and Rejection of Sick Role. Scales based on this set of items have been found to correlate with more specific indices of health status such as number of days in bed, presence of chronic illness, limitations in role activity, presence of pain, and absence of psychological well-being. They are also significantly related to specific health behaviors, including number of doctor visits, recency of care, and hospitalization. Two subscales (Current Health and Health Worry/Concern) have been found to correlate with compliance (Ware, Davies-Avery and Donald, 1978). General health scales were included in the study as generalized self-rated outcome measures and because they have the potential for explaining other variables; a patient's subjective assessment of his or her general health status may be an important factor in determining both perceived need for and actual use of a drug.

#### ATTITUDE TOWARD MEDICATION (GENERAL)

The information contained in PPIs may affect not only how the individual feels about a particular drug but also how that person feels about other prescription drugs. To assess possible effects on these more general attitudes, the mail follow-up questionnaire included a set of items measuring beliefs about the safety and appropriateness of taking prescription drugs. Four of these items were adapted from a previous FDA-sponsored study (Kanouse and Morris, 1978).[4] Other items

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[4]A factor analysis of the data in that study indicated that although the items appear to measure the hypothesized construct (attitude toward drug-taking), the wording of one of the items also produced a high item-loading on a factor representing attitudes toward physicians. Accordingly, the wording for that item was altered.

were adapted from a study of physicians' attitudes toward drugs (Linn, 1971), where they were found to be significantly related to physicians' acceptance of the use of Dexedrine and Librium.

#### HEALTH LOCUS OF CONTROL

Health locus of control (HLC) is an individual difference measure presumed to reflect the tendency to perceive health outcomes as determined by one's own behavior (internal) or by other factors (external). It has been found to correlate with a variety of health-related behaviors, including information-seeking (Toner and Manuck, 1979; Wallston, Maides, and Wallston, 1976), smoking (James, Woodruff, and Werner, 1965), and use of seat belts (Williams, 1972). Moreover, several studies have found health intervention programs to be differentially successful for internals and externals (Best, 1975; Best and Steffy, 1975; Manno and Marston, 1972; Wallston et al., 1976). Programs stressing patient involvement seem to be more successful with internally oriented individuals, whereas programs stressing the controllability of health outcomes (e.g., by health professionals) may be more successful for external individuals. Each of the PPIs to be used in this study recommends certain actions the individual can take in initiating, carrying out, and monitoring drug therapy. The individual's belief in the effectiveness of his or her own actions may affect the extent to which these recommendations are followed.

A leaflet aimed at educating the patient about specific behaviors that may improve the outcomes of drug therapy may itself produce changes in HLC toward greater internality. The possibility that individuals can

be trained in internality has received recent attention in the literature (Green, Levine, and Deeds, 1975; Hamid and Flay, 1974; Roter, 1977). A number of investigators have suggested that providing information to patients increases their sense of "informational control" (Averill, 1973; Krantz and Schulz, 1979), which in turn may influence certain health outcomes such as the ability to tolerate medical procedures without undue discomfort (Egbert et al., 1964; Johnson, 1975; Johnson and Leventhal, 1974; Taylor, 1979).

The HLC measure chosen for this study incorporates recent developments in the conceptualization and measurement of the HLC construct. The original HLC scale was developed as a unidimensional measure designed to yield a single score (Wallston et al., 1976). Recent evidence indicates that the scale is in fact multidimensional. New scales have been developed to tap this multidimensional structure (Lau and Ware, in press; Wallston, Wallston, and DeVellis, 1978). The scale developed by Lau and Ware, unlike the Wallston scale, is balanced to control for agreement response bias, so we chose items from it.

The scale comprises four subscales:

<u>Subscale</u>	<u>Definition</u>
Self-care	Belief that people can (cannot) control their own health outcomes.
Provider	Belief that medical care and doctors can (cannot) help people get well, feel better.
Difficult World	Belief that some diseases are (are not) so serious that nothing can be done about them.
Chance	Belief that chance does (does not) play a large role in determining health outcomes.

We included four items from each of the first two scales above and two items from each of the last two. Data on factor loadings and discriminant validity were used in selecting the items.

#### DESIRE FOR INFORMATION-GIVING AND RESPONSIBILITY

Numerous studies have shown that patients typically want more information about their illness and therapy than they either get or explicitly ask for (Faden et al., 1981; Kutner, 1958; Pratt, Seligman, and Reader, 1957; Reader, Pratt, and Mudd, 1957; Roth, 1963; Skipper, Tagliacozzo, and Mauksch, 1964; Tagliacozzo and Mauksch, 1972). Little attention has been directed to the question of individual differences in the desire for information-giving. Although many patients undoubtedly want a great deal more information than they receive, others probably do not. Because informational preferences may influence patients' response to written drug information, items designed to measure those preferences were included in the follow-up questionnaire.[5] Analysis of these items can reveal whether the experimental intervention affects the value placed on information-giving. It is possible, for example, that those who receive drug information and find it useful will come to place higher value on receiving such information in the future.

A similar rationale underlies the inclusion of items designed to measure desire for patient responsibility. Although the concept of self-care is not new (Green et al., 1977; Levin, Katz, and Holst, 1976), consumers' attitudes toward the proper allocation of responsibility for

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[5]A similar set of items has been recently and independently developed by Krantz, Baum, and Wideman (1980).

health care have received little attention in the research literature.[6] Consumers' views concerning participation in the medical decisionmaking process are important; this research will explore the relationship between those views and the effects of receiving drug information.

#### SATISFACTION WITH DOCTOR INFORMATION-GIVING

Several studies have found that the amount of information and explanation provided by physicians are important determinants of patient satisfaction with health care (DiMatteo and Hays, 1980; Fisher, 1971; Houston and Pasanen, 1972; Korsch, Gozzi, and Francis, 1968; Stiles et al., 1979; Ware and Doyle, 1977; Wriglesworth and Williams, 1975). In the present study, PPIs may increase patient satisfaction by providing more information, or decrease satisfaction by setting a standard against which doctor information-giving is negatively evaluated. Either way, the study's measure of patient satisfaction provides information about the effects PPIs are likely to have on patient views concerning the doctor-patient relationship. These effects are of major concern to the medical community (Institute of Medicine, 1979b).

#### ATTITUDE TOWARD MEDICAL RISK/RISK EXPLANATION

Four items in the mail questionnaire were designed to measure subjects' beliefs concerning the amount of risk to which doctors expose their patients and whether doctors explain those risks to the patient.

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[6]Again, Krantz and his associates (Krantz, 1978; Krantz, Baum, and Wideman, 1980) have also developed a set of items to measure preferences for active participation in treatment.



These variables should be related to the amount of vigilance patients wish to maintain over their own therapy. Those who believe that doctors are effective at assessing risk and conscientious about informing their patients should be less vigilant than those who believe that doctors fall short on either score.

The study design permits us to examine these variables both as dependent variables (i.e., to ascertain whether receipt of drug information affects patients' beliefs about risks and risk explanation) and as mediating variables, to determine whether beliefs about risk and risk explanation affect the individual's use of the PPI.

#### PERCEIVED MEDICAL CONSENSUS REGARDING TREATMENT

This variable was measured by two items taken from a longer scale used in Rand's Health Insurance Study to measure "medical sophistication" (Newhouse, Ware, and Donald, 1981). The two items measure a specific component of sophistication: namely, the belief that experts may disagree about the correct way to treat an illness. Those who believe that the recommendations of a given doctor carry the full weight of consensual medical authority may not question the doctor's advice or seek out and weigh other information. In contrast, those who believe that there is room for disagreement even among experts may pay attention to other information sources, whether second opinions or PPIs; they may also take a more active role in decisionmaking about their therapy. These beliefs may help identify those who adopt an active role as health consumers (Galiher, Needleman, and Rolfe, 1971; Green, 1975).

ATTITUDES TOWARD TAKING THE DRUG

Patients' attitudes toward taking the medication were assessed in the mail follow-up questionnaire by means of semantic differential scales, adapted from a study of consumer attitudes toward the swine flu vaccine.[7] Ratings on these scales permit us to determine whether different versions of the PPI result in different attitudes about taking the drug in question.[8]

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[7]The swine flu study was conducted in 1977 by the Lexington Health Department, Fayette County, Kentucky, under the direction of Philip G. Weiler, M.D.

[8]In addition to the variables discussed above, the mail questionnaire contained a short series of questions on respondents' prescription-filling behavior. These questions were included in the survey to provide additional information on pharmacy patronage habits and motives that might be helpful in explaining variations in outcome measures associated with pharmacy milieu.

## VI. STRENGTHS AND LIMITATIONS

The study we have described has several strengths that distinguish it from previous research. First, it applies rigorous experimental procedures within a natural context, one that applies to a very wide range of prescription drug users. In contrast, most previous studies that are comparably well-controlled draw upon clinic or hospital populations (e.g., Dwyer and Hammel, 1978; Kanouse and Morris, 1978; Udkow et al., 1979) or employ convenience samples of people who are not actually using the drug (e.g., Keown, 1980; Morris and Kanouse, 1980, 1981; Stergachis, Johnson, and Bootman, 1980). Second, no previous study has examined so broad a range of outcomes, ranging from compliance and clinical course to generalized attitudes toward medication. This is especially important in the light of the numerous empirical questions that have been raised about PPIs. Third, no previous study has attempted to measure outcomes for such a diverse sample of drug users, permitting an unusual degree of confidence in the generalizability of the findings.

Despite these strengths, the study also has limitations. First, the sample excludes certain subgroups whose interests need to be represented in public policy. Among these are the seriously ill and the institutionalized (largely excluded from our sample because of the restriction to patients picking up their own prescriptions) and the non-English speaking. In addition, the sample underrepresents patients who use prescription drugs infrequently, or who are using the study drug

for the first time.[1] Because such patients might respond to PPIs differently from chronic users,[2] their underrepresentation could lead to a corresponding underestimation of PPI effects. However, the study merely underrepresents such patients; it does not exclude them. Thus, if the sample of new or infrequent users is large enough, it is possible to make separate estimates of PPI effects for these groups.

The study's findings may also be constrained by the methodology used to collect the data. Because subjects were approached about study participation before they received an experimental PPI, their responses to the PPI may have been shaped to some extent by the fact that they were participating in a study. For example, subjects in this study may have been more likely to read the PPI than they would be in other circumstances. Unfortunately, there is no way of determining for certain whether subjects' responses were affected by their participation.[3] Any biasing effects of study participation were present in all experimental conditions, however. Because there is no reason to suppose that subjects would be differentially affected by study participation in different PPI conditions, the study should provide sound information on the effects associated with different types of PPIs.

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[1]The reason for this underrepresentation is that chronic drug users fill more prescriptions than infrequent users or new users. The former are therefore more likely to walk into a pharmacy to fill a prescription during the course of the study and consequently be included in the sample. Because the effective sampling unit is the individual prescription rather than the individual drug user, the sample does not provide equal representation for all types of people who ever use a given drug.

[2]For example, those who have no experience with a drug may be more influenced by written information they receive about it.

[3]The additional control group or groups that would be required to resolve this question were excluded from the design because they would violate guidelines for conducting research with human subjects.

Finally, any study is necessarily limited in its ability to inform about the long-term effects of PPIs should they become commonplace. The effects of these documents as currently measured may be influenced by their novelty, which, under a program of wide distribution, would inevitably wear off with time. However, widespread distribution of PPIs might have cumulative effects (e.g., on patients' general awareness of the importance of proper use of prescription drugs) that are not readily apparent from responses to a one-time PPI (Institute of Medicine, 1979).

Obviously, current research cannot fully capture the informational context in which PPIs might eventually be distributed. This limitation is not a very telling one, however. The qualitative responses revealed in the present study (and in other research on PPIs) are probably a good indication of the kinds of effects that can be expected; widespread distribution is more likely to alter the magnitude of these effects than their direction.

Despite the study's limitations, its results provide a rich body of information on how patients respond to PPIs. They also provide important information on the effects of several design variables that are, in principle, under FDA's regulatory control.

In addition to its relevance to those concerned with the issue of patient drug labeling, the study and its findings should interest those who are concerned with the generic problems of product labeling (Miller, 1978; Morris, Mazis, and Barofsky, 1980) and the broader question of how information can be most effectively designed for consumers (Bettman, 1975; Houston and Rothschild, 1980; Hutton, McNeill, and Wilkie, 1978).

The growth of the consumer movement and the concomitant increase in the pressure on regulators and manufacturers alike to provide more and better information have made us increasingly aware of the gaps in our knowledge about how to provide such information. This study helps fill some of those gaps.

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Appendix A

EXPERIMENTAL LEAFLETS

explanation/no specific instructions

S-1-2

# ESTROGENS

(S-trow-gens)

Estrogens are hormones used to treat symptoms of the menopause. Like all drugs, they have both benefits and risks. You should understand both benefits and risks before deciding to take estrogens. This leaflet contains important information about estrogens and your health. Read it and save it for future reference.

The first part of the leaflet summarizes the basic facts about estrogens. Later parts of the leaflet give more detailed information about what estrogens are, why people use them, and how to use estrogens. The last part of the leaflet tells you what precautions to take when using estrogens and what dangers and side effects might occur. If you would like additional information about estrogens, contact your doctor or your pharmacist. Your pharmacist can give you a more technical leaflet to read.

## SUMMARY

Estrogens are female hormones. They help regulate a woman's sexual development and menstrual cycle.

Doctors usually prescribe estrogens to treat uncomfortable symptoms of the menopause, such as "hot flashes" and painful changes in the vagina. For symptoms of the menopause, your doctor may recommend that you take estrogens on a four week cycle, three weeks on the estrogens followed by one week off. In general, take the lowest dose of estrogens possible for as short a time as possible.

Doctors also use estrogens to treat certain cancers in women and men, to speed up abnormally slow sexual development, or to prevent post-partum breast engorgement. Birth control pills also contain estrogens.

Estrogens have important uses but can cause serious health problems and many side effects. Pregnant women should never take estrogens. Nursing mothers, and women who have had liver problems, a stroke, heart attack or angina pectoris should discuss these problems with their doctor before taking estrogens. Women who have a family history of breast

cancer, or who have had abnormal vaginal bleeding should also discuss this with their doctor before taking estrogens.

Estrogens may increase the risk of endometrial cancer, liver tumors, abnormal blood clotting, gallbladder disease, and growth of non-cancerous tumors. Discuss these things with your doctor before deciding to take estrogens.

## WHAT ESTROGENS ARE

Estrogens are female hormones produced by the ovaries. In addition, scientists can make different kinds of synthetic estrogens. Estrogens produced by the body cause the changes that occur in girls at puberty. For example, they cause girls' breasts to grow larger and they cause girls to begin menstruating. Estrogens also regulate a woman's menstrual cycle throughout her life.

## USES OF ESTROGENS

**TO RELIEVE SYMPTOMS OF THE MENOPAUSE.** There are two kinds of menopause: "natural" menopause and "surgical" menopause. Natural menopause usually occurs between the ages of 45 and 55. Surgical menopause occurs if a doctor removes a woman's ovaries before the natural menopause occurs.

During menopause, your body produces less estrogen. As a result, you may have some uncomfortable "vasomotor" symptoms. You may have "hot flashes" or "hot flushes." You may suddenly feel hot and sweaty all over your body. You may develop changes in your vagina (called atrophic vaginitis). The estrogens you take replace some of the natural estrogens. This helps to relieve these symptoms.

Estrogens cannot relieve all of the symptoms of menopause. For example, you may feel nervous or depressed during the menopause. Estrogens will not relieve these symptoms and they will not make you feel young or keep your skin soft. In fact, estrogens cause some women to become depressed.

**TO PREVENT POST-PARTUM BREAST ENGORGEMENT.** If you are pregnant, you may plan not to breast-feed your child. In that case, your doctor may give you estrogens immediately after delivery to prevent your breasts from swelling. However, a large dose is necessary and doesn't always work. Such large doses increase the risk that you will develop a blood clot in your legs or lungs. In

addition, milk-filled breasts usually cause only minor discomfort and you can treat them in other ways. You can take aspirin to relieve the pain and you can bind your breasts to prevent them from swelling.

**TO TREAT HYPOGONADISM.** Sometimes doctors prescribe estrogens to treat "hypogonadism." This is a condition in which a girl's sex organs do not develop normally. Her breasts may not grow normally and she may not begin menstruating.

**OTHER USES OF ESTROGENS.** Your doctor may have prescribed estrogens to treat cancer or a certain bone disease called osteoporosis. Many birth control pills also contain estrogens.

## HOW TO USE ESTROGENS

If you are taking estrogens to treat symptoms of the menopause, you should take them on a four week cycle. Take the estrogens for three weeks, skip a week and then begin again. Your doctor may want you to try to stop taking the estrogens or decrease the dosage every three to six months. In general, you should take as little as possible for as short a time as possible.

Different women react differently during menopause so they have different needs for estrogens. At least half of the women who go through menopause have no problems at all or only mild ones. If you are one of these women you do not need to take estrogens. But, if you have symptoms that make you uncomfortable, you may need to take estrogens for a few months. After your body adjusts to the lower estrogen levels, you won't have to take it anymore. Finally, you may have long-lasting uncomfortable symptoms of the menopause. If so, you may need to take estrogens longer than six months. If you have to take estrogens for a long time, ask your doctor to examine you at least twice a year to see if you can stop taking the estrogens.

If you are taking estrogens to treat cancer or for some other reason, your doctor will tell you how much to take and how often to take it.

## PRECAUTIONS

Estrogens are powerful drugs. Don't take them unless you have a serious need for them and there is no other treatment. Discuss the risks and benefits of estrogens with your doctor before deciding to take them. In addition, pregnant women, nursing mothers, and women who have had liver problems should never take estrogens.

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If you take estrogens while you are pregnant, it could seriously damage your child. Female children whose mothers have taken a certain kind of estrogens (diethylstilbestrol) during pregnancy have a higher risk of getting vaginal and cervical cancer later in life. About four out of every 1000 girls whose mothers take estrogens may get this kind of cancer. Many more of these girls (30-90%) may get changes in the lining of the vagina and cervix called "vaginal adenosis." These changes could also turn into cancer.

Estrogens can also give your child heart defects or abnormally small arms or legs. Studies suggest that one out of every one thousand children whose mothers take estrogens will have abnormally small arms or legs. This risk is five times greater than the risk for children whose mothers do not take estrogens. If you are pregnant and you have already taken some estrogens, stop taking the estrogens immediately and consult your doctor.

If you are nursing, estrogens can get into your milk and pass to your child. It is not known whether estrogens might hurt your child.

Discuss your medical history with your doctor before deciding to take estrogens. This is especially important if you have any of the following problems.

If you have ever had hepatitis, cirrhosis of the liver, or other liver problems, do not take estrogens. Taking estrogens can make your liver problems worse. Signs of liver problems include itching, light-colored bowel movements, dark urine, stomach pain or yellowing of the skin or eyes. If you have ever had any of these symptoms, call your doctor immediately and do not take estrogens.

If you have had a stroke or a heart attack or if you have angina pectoris, estrogens might increase your chance of having another attack.

Estrogens might speed up the development of breast cancer. If you or other women in your family have had breast cancer, breast lumps, fibrocystic disease or abnormal mammograms, discuss this with your doctor before deciding to take estrogens. Also, do monthly breast examinations on yourself and tell your doctor if you notice any changes in your breasts.

If you have certain other medical conditions, taking estrogens might make them worse. These include: bone disease, blood clots, abnormal vaginal bleeding, epilepsy, migraine headaches, high levels of calcium in your blood, or problems with your kidneys. If you

have any of these medical conditions, discuss them with your doctor before deciding to take estrogens.

Finally, if you plan to have certain medical procedures, make sure your doctor knows you are taking estrogens. If you have surgery that requires you to remain in bed for a long time, you might develop a blood clot. If you take estrogens at the same time, you increase the risk of getting a blood clot. Taking estrogens can also affect the results of some lab tests. If you plan to have any of these medical procedures, tell your doctor that you are taking estrogens.

This drug is for you only. Do not give it to anyone else. Keep estrogens and all medicines where children cannot reach them.

## DANGERS OF ESTROGENS

Estrogens can cause several serious health problems. Discuss these possible problems with your doctor before deciding to take estrogens. If you are already taking estrogens and have any symptoms of the following health problems, call your doctor.

**ENDOMETRIAL CANCER.** Taking estrogens increases your chance of getting endometrial cancer (cancer of the lining of the uterus). If you use estrogens your chance of getting endometrial cancer is 4-14 times greater. If you take estrogens continuously, your risk will be greater than if you take it in cycles (three weeks on, one week off). If you take large doses of estrogens or if you take it for a long time you will face a great risk of cancer. If you have abnormal bleeding from your vagina, you may have endometrial cancer. Note: If you have had your uterus removed (hysterectomy) there is no danger of endometrial cancer.

**STROKE, HEART ATTACK, and BLOOD CLOTS.** Taking estrogens might increase the risk of a stroke, a heart attack, or a blood clot. If you have pain in your calves or chest, shortness of breath, dizziness, headaches, or changes in vision, or if you start coughing blood, you may have a blood clot.

**LIVER TUMORS.** Taking estrogens may increase the risk of benign (non-cancerous) tumors of the liver. These tumors do not occur very often. But when they do occur, they can rupture and cause internal bleeding.

**FIBROID TUMORS.** Taking estrogens may cause existing fibroid tumors in the uterus to get larger. These tumors are not serious, but if

they grow you may have to have surgery to remove them.

**OTHER TUMORS.** Taking estrogens might also cause tumors of the breast, cervix or vagina.

**GALLBLADDER DISEASE.** Estrogens may increase the chance of gallbladder disease. A recent study reported that women who take estrogens are 2-3 times more likely to get gallbladder disease than women who do not take estrogens.

**HIGH BLOOD PRESSURE.** Estrogens can cause high blood pressure. However, after you stop taking estrogens your blood pressure will usually return to normal.

## SIDE EFFECTS

Side effects are unwanted effects caused by a drug. Estrogens may cause many side effects, including the following:

1. Vaginal -- bleeding from the vagina (other than your usual monthly period), a change in the amount of menstrual bleeding, missed menstrual period, painful menstrual periods or depression and bloating similar to pre-menstrual depression and bloating, fungus or yeast infection of the vagina (itching or change in mucus), pain or burning feeling during urination.
2. Breast -- enlargement or tenderness, leaking fluids from the breasts.
3. Stomach and intestines -- nausea, vomiting, cramps or pain in the stomach.
4. Skin -- temporary or permanent brown spots on the skin, skin rash, loss of hair from the head or increase in amount of hair on the body.
5. Head and eyes -- headaches, including migraines or dizziness, change in vision, problems with wearing contact lenses.
6. Miscellaneous -- increase or decrease in weight, uncontrollable jerking motions of the body, change in desire for sex (increase or decrease).

Prepared and distributed by: Prescription Drug Labeling  
5800 Fishers Lane  
Rockville, Maryland 20857

September 1979

*no explanation/specific instructions*

S-1-3

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Doctors also use estrogens to treat certain cancers in women and men, to speed up abnormally slow sexual development, or to prevent post-partum breast engorgement. Birth control pills also contain estrogens.

Estrogens have important uses but can cause serious health problems and many side ef-

fects. Pregnant women should never take estrogens. Nursing mothers, and women who have had liver problems, a stroke, heart attack or angina pectoris should discuss these problems with their doctor before taking estrogens. Women who have a family history of breast cancer, or who have had abnormal vaginal bleeding should also discuss this with their doctor before taking estrogens.

Estrogens may increase the risk of endometrial cancer, liver tumors, abnormal blood clotting, gallbladder disease, and growth of non-cancerous tumors. Discuss these things with your doctor before deciding to take estrogens.

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Estrogens are female hormones produced by the ovaries. They regulate a woman's menstrual cycle throughout her life.

### USES OF ESTROGENS

**TO RELIEVE SYMPTOMS OF THE MENOPAUSE.** There are two kinds of menopause: "natural" menopause and "surgical" menopause. Natural menopause usually occurs between the ages of 45 and 55. Surgical menopause occurs if a doctor removes a woman's ovaries before the natural menopause occurs.

During menopause, you may have some uncomfortable "vasomotor" symptoms. You may have "hot flashes" or "hot flushes." You may suddenly feel hot and sweaty all over your body. You may develop changes in your vagina (called atrophic vaginitis). Estrogens can relieve these symptoms.

Estrogens cannot relieve all of the symptoms of menopause. For example, you may feel nervous or depressed during the menopause. Estrogens will not relieve these symptoms and they will not make you feel young or keep your skin soft. In fact, estrogens cause some women to become depressed.

**TO PREVENT POST-PARTUM BREAST ENGORGEMENT.** If you are pregnant, you may plan not to breast-feed your child. In that case, your doctor may give you estrogens immediately after delivery to prevent your breasts from swelling. However, a large dose is necessary and doesn't always work. In

addition, milk-filled breasts usually cause only minor discomfort and you can treat them in other ways.

**TO TREAT HYPOGONADISM.** Sometimes doctors prescribe estrogens to treat "hypogonadism." This is a condition in which a girl's sex organs do not develop normally.

**OTHER USES OF ESTROGENS.** Your doctor may have prescribed estrogens to treat cancer or a certain bone disease called osteoporosis. Many birth control pills also contain estrogens.

### HOW TO USE ESTROGENS

If you are taking estrogens to treat symptoms of the menopause, you should take them on a four week cycle. Take the estrogens for three weeks, skip a week and then begin again. Your doctor may want you to try to stop taking the estrogens or decrease the dosage every three to six months.

In general, take the smallest possible dose of estrogens for as short a time as possible. Take the smallest dose that will control your symptoms. Keep track of your symptoms. Tell your doctor if you think your symptoms are getting better. Your doctor may advise you to stop taking the estrogens for several weeks to see if you can live comfortably without them. Ask your doctor for a new prescription only if your symptoms become very uncomfortable.

If you have to take estrogens for a long time, ask your doctor to examine you at least twice a year to see if you can stop taking the estrogens. Set up your appointments well in advance to make sure you don't forget them. Ask your doctor to include a Pap smear and to examine you for early signs of trouble. Also ask your doctor to review the risks and benefits of estrogens with you.

If you are taking estrogens to treat cancer or for some other reason, your doctor will tell you how much to take and how often to take it.

### PRECAUTIONS

Estrogens are powerful drugs. Don't take them unless you have a serious need for them and there is no other treatment. Discuss the

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risks and benefits of estrogens with your doctor before deciding to take them. You may not know if you have had some of the medical problems listed below. If you are unsure, contact your previous doctor or hospital and ask that your records be sent to your present doctor. In addition, pregnant women, nursing mothers, and women who have had liver problems should never take estrogens.

If you take estrogens while you are pregnant, it could seriously damage your child. Female children whose mothers have taken a certain kind of estrogens (diethylstilbestrol) during pregnancy have a higher risk of getting vaginal and cervical cancer later in life. It could give your child heart defects or abnormally small arms or legs. If you are pregnant and you have already taken some estrogens, stop taking the estrogens immediately and consult your doctor.

If you are nursing, estrogens can get into your milk and pass to your child. It is not known whether estrogens might hurt your child. If you are nursing a child and you have already taken some estrogens, stop taking the estrogens and consult your doctor.

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problems listed below. If you are unsure, contact your previous doctor or hospital and ask that your records be sent to your present doctor. In addition, pregnant women, nursing mothers, and women who have had liver problems should never take estrogens.

If you take estrogens while you are pregnant, it could seriously damage your child. Female children whose mothers have taken a certain kind of estrogens (diethylstilbestrol) during pregnancy have a higher risk of getting vaginal and cervical cancer later in life. About four out of every 1000 girls whose mothers take estrogens may get this kind of cancer. Many more of these girls (30-90%) may get changes in the lining of the vagina and cervix called "vaginal adenosis." These changes could also turn into cancer.

Estrogens can also give your child heart defects or abnormally small arms or legs. Studies suggest that one out of every one thousand children whose mothers take estrogens will have abnormally small arms or legs. This risk is five times greater than the risk for children whose mothers do not take estrogens. If you are pregnant and you have already taken some estrogens, stop taking the estrogens immediately and consult your doctor.

If you are nursing, estrogens can get into your milk and pass to your child. It is not known whether estrogens might hurt your child. If you are nursing a child and you have already taken some estrogens, stop taking the estrogens and consult your doctor.

Discuss your medical history with your doctor before deciding to take estrogens. This is especially important if you have any of the following problems.

If you have ever had hepatitis, cirrhosis of the liver, or other liver problems, do not take estrogens. Signs of liver problems include itching, light-colored bowel movements, dark urine, stomach pain or yellowing of the skin or eyes. If you have ever had any of these symptoms, call your doctor immediately and do not take estrogens.

If you have had a stroke or a heart attack or if you have angina pectoris, estrogens might increase your chance of having another attack.

Estrogens might speed up the development of breast cancer. If you or other women in your family have had breast cancer, breast lumps, fibrocystic disease or abnormal mammograms, discuss this with your doctor before deciding to take estrogens. Also, do monthly breast examinations on yourself and tell your doctor if you notice any changes in your breasts. Ask your doctor to show you the proper way to examine your breasts.

If you have certain other medical conditions, taking estrogens might make them worse. These include: bone disease, blood clots, abnormal vaginal bleeding, epilepsy, migraine headaches, high levels of calcium in your blood, or problems with your kidneys. If you have any of these medical conditions, discuss them with your doctor before deciding to take estrogens.

Finally, if you plan to have certain medical procedures, make sure your doctor knows you are taking estrogens. If you have surgery that requires you to remain in bed for a long time, you might develop a blood clot. If you take estrogens at the same time, you increase the risk of getting a blood clot. Taking estrogens can also affect the results of some lab tests. If you plan to have any of these medical procedures, tell your doctor that you are taking estrogens.

This drug is for you only. Do not give it to anyone else. Keep estrogens and all medicines where children cannot reach them. For example, store them on a high shelf or in a locked cupboard.

## DANGERS OF ESTROGENS

Estrogens can cause several serious health problems. Discuss these possible problems with your doctor before deciding to take estrogens. If you are already taking estrogens and have any symptoms of the following health problems, call your doctor.

**ENDOMETRIAL CANCER.** Taking estrogens increases your chance of getting endometrial cancer (cancer of the lining of the uterus). If you use estrogens your chance of getting endometrial cancer is 4-14 times greater. If you take estrogens continuously, your risk will be greater than if you take it in cycles (three weeks on, one week off). If you take large doses of estrogens or if you take it for a long time you will face a great risk of cancer. If you have abnormal bleeding from your vagina, you may have endometrial cancer. Note: If you have had your uterus removed (hysterectomy) there is no danger of endometrial cancer.

**STROKE, HEART ATTACK, and BLOOD CLOTS.** Taking estrogens might increase the risk of a stroke, a heart attack, or a blood clot. If you have pain in your calves or chest, shortness of breath, dizziness, headaches, or changes in vision, or if you start coughing blood, you may have a blood clot.

**LIVER TUMORS.** Taking estrogens may increase the risk of benign (non-cancerous) tumors of the liver. These tumors do not occur very often. But when they do occur, they can rupture and cause internal bleeding.

**FIBROID TUMORS.** Taking estrogens may cause existing fibroid tumors in the uterus to get larger. These tumors are not serious, but if they grow you may have to have surgery to remove them.

**OTHER TUMORS.** Taking estrogens might also cause tumors of the breast, cervix or vagina.

**GALLBLADDER DISEASE.** Estrogens may increase the chance of gallbladder disease. A recent study reported that women who take estrogens are 2-3 times more likely to get gallbladder disease than women who do not take estrogens.

**HIGH BLOOD PRESSURE.** Estrogens can cause high blood pressure. However, after you stop taking estrogens your blood pressure will usually return to normal.

## SIDE EFFECTS

Side effects are unwanted effects caused by a drug. Estrogens may cause many side effects, including the following:

1. Vaginal -- bleeding from the vagina (other than your usual monthly period), a change in the amount of menstrual bleeding, missed menstrual period, painful menstrual periods or depression and bloating similar to pre-menstrual depression and bloating, fungus or yeast infection of the vagina (itching or change in mucous), pain or burning feeling during urination.
2. Breast -- enlargement or tenderness, leaking fluids from the breasts.
3. Stomach and intestines -- nausea, vomiting, cramps or pain in the stomach.
4. Skin -- temporary or permanent brown spots on the skin, skin rash, loss of hair from the head or increase in amount of hair on the body.
5. Head and eyes -- headaches, including migraines or dizziness, change in vision, problems with wearing contact lenses.
6. Miscellaneous -- increase or decrease in weight, uncontrollable jerking motions of the body, change in desire for sex (increase or decrease).

Prepared and distributed by:  
5800 Fishers Lane  
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Core version

no explanation  
no specific instructions  
simplified writing  
no risk emphasis  
text format  
full content

S-2-1

## ESTROGENS

(S-trow-gens)

Estrogens are hormones used to treat symptoms of the menopause. Like all drugs, they have both benefits and risks. You should understand both benefits and risks before deciding to take estrogens. This leaflet contains important information about estrogens and your health. Read it and save it for future reference.

The first part of the leaflet summarizes the basic facts about estrogens. Later parts of the leaflet give more detailed information about what estrogens are, why people use them, and how to use estrogens. The last part of the leaflet tells you what precautions to take when using estrogens and what dangers and side effects might occur. If you would like additional information about estrogens, contact your doctor or your pharmacist. Your pharmacist can give you a more technical leaflet to read.

### SUMMARY

Estrogens are female hormones. They help regulate a woman's sexual development and menstrual cycle.

Doctors usually prescribe estrogens to treat uncomfortable symptoms of the menopause, such as "hot flashes" and painful changes in the vagina. For symptoms of the menopause, your doctor may recommend that you take estrogens on a four week cycle, three weeks on the estrogens followed by one week off. In general, take the lowest dose of estrogens possible for as short a time as possible.

Doctors also use estrogens to treat certain cancers in women and men, to speed up abnormally slow sexual development, or to prevent post-partum breast engorgement. Birth control pills also contain estrogens.

Estrogens have important uses but can cause serious health problems and many side effects. Pregnant women should never take estrogens. Nursing mothers, and women who have had liver problems, a stroke, heart attack or angina pectoris should discuss these problems with their doctor before taking estrogens. Women who have a family history of breast cancer, or who have had abnormal vaginal bleeding should also discuss this with their doctor before taking estrogens.

Estrogens may increase the risk of endometrial cancer, liver tumors, abnormal blood clotting, gallbladder disease, and growth of non-cancerous tumors. Discuss these things with your doctor before deciding to take estrogens.

### WHAT ESTROGENS ARE

Estrogens are female hormones produced by the ovaries. They regulate a woman's menstrual cycle throughout her life.

### USES OF ESTROGENS

**TO RELIEVE SYMPTOMS OF THE MENOPAUSE.** There are two kinds of menopause: "natural" menopause and "surgical" menopause. Natural menopause usually occurs between the ages of 45 and 55. Surgical menopause occurs if a doctor removes a woman's ovaries before the natural menopause occurs.

During menopause, you may have some uncomfortable "vasomotor" symptoms. You may have "hot flashes" or "hot flushes." You may suddenly feel hot and sweaty all over your body. You may develop changes in your vagina (called atrophic vaginitis). Estrogens can relieve these symptoms.

Estrogens cannot relieve all of the symptoms of menopause. For example, you may feel nervous or depressed during the menopause. Estrogens will not relieve these symptoms and they will not make you feel young or keep your skin soft. In fact, estrogens cause some women to become depressed.

**TO PREVENT POST-PARTUM BREAST ENGORGEMENT.** If you are pregnant, you may plan not to breast-feed your child. In that case, your doctor may give you estrogens immediately after delivery to prevent your breasts from swelling. However, a large dose is necessary and doesn't always work. In addition, milk-filled breasts usually cause only minor discomfort and you can treat them in other ways.

**TO TREAT HYPOGONADISM.** Sometimes doctors prescribe estrogens to treat "hypogonadism." This is a condition in which a girl's sex organs do not develop normally.

**OTHER USES OF ESTROGENS.** Your doctor may have prescribed estrogens to treat cancer or a certain bone disease called osteoporosis. Many birth control pills also contain estrogens.

### HOW TO USE ESTROGENS

If you are taking estrogens to treat symptoms of the menopause, you should take them on a four week cycle. Take the estrogens for three weeks, skip a week and then begin again. Your doctor may want you to try to stop taking the estrogens or decrease the dosage every three to six months. In general, you should take as little as possible for as short a time as possible.

If you have to take estrogens for a long time, ask your doctor to examine you at least twice a year to see if you can stop taking the estrogens.

If you are taking estrogens to treat cancer or for some other reason, your doctor will tell you how much to take and how often to take it.

### PRECAUTIONS

Estrogens are powerful drugs. Don't take them unless you have a serious need for them and there is no other treatment. Discuss the risks and benefits of estrogens with your doctor before deciding to take them. In addition, pregnant women, nursing mothers, and women who have had liver problems should never take estrogens.

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If you take estrogens while you are pregnant, it could seriously damage your child. Female children whose mothers have taken a certain kind of estrogen (diethylstilbestrol) during pregnancy have a higher risk of getting vaginal and cervical cancer later in life. It could give your child heart defects or abnormally small arms or legs. If you are pregnant and you have already taken some estrogens, stop taking the estrogens immediately and consult your doctor.

If you are nursing, estrogens can get into your milk and pass to your child. It is not known whether estrogens might hurt your child.

Discuss your medical history with your doctor before deciding to take estrogens. This is especially important if you have any of the following problems.

If you have ever had hepatitis, cirrhosis of the liver, or other liver problems, do not take estrogens. Signs of liver problems include itching, light-colored bowel movements, dark urine, stomach pain or yellowing of the skin or eyes. If you have ever had any of these symptoms, call your doctor immediately and do not take estrogens.

If you have had a stroke or a heart attack or if you have angina pectoris, estrogens might increase your chance of having another attack.

Estrogens might speed up the development of breast cancer. If you or other women in your family have had breast cancer, breast lumps, fibrocystic disease or abnormal mammograms, discuss this with your doctor before deciding to take estrogens. Also, do monthly breast examinations on yourself and tell your doctor if you notice any changes in your breasts.

If you have certain other medical conditions, taking estrogens might make them worse. These include: bone disease, blood clots, abnormal vaginal bleeding, epilepsy, migraine headaches, high levels of calcium in your blood, or problems with your kidneys. If you have any of these medical conditions, discuss them with your doctor before deciding to take estrogens.

Finally, if you plan to have certain medical procedures, make sure your doctor knows you are taking estrogens. If you plan to have surgery that requires you to remain in bed for a long time or if you plan to have any lab tests, tell your doctor that you are using estrogens.

This drug is for you only. Do not give it to anyone else. Keep estrogens and all medicines where children cannot reach them.

## DANGERS OF ESTROGENS

Estrogens can cause several serious health problems. Discuss these possible problems with your doctor before deciding to take estrogens. If you are already taking estrogens and have any symptoms of the following health problems, call your doctor.

**ENDOMETRIAL CANCER.** Taking estrogens increases your chance of getting endometrial cancer (cancer of the lining of the uterus). If you take estrogens continuously, your risk will be greater than if you take it in cycles (three weeks on, one week off). If you take large doses of estrogens or if you take it for a long time you will face a great risk of cancer. If you have abnormal bleeding from your vagina, you may have endometrial cancer. Note: If you have had your uterus removed (hysterectomy) there is no danger of endometrial cancer.

**STROKE, HEART ATTACK, and BLOOD CLOTS.** Taking estrogens might increase the risk of a stroke, a heart attack, or a blood clot. If you have pain in your calves or chest, shortness of breath, dizziness, headaches, or changes in vision, or if you start coughing blood, you may have a blood clot.

**LIVER TUMORS.** Taking estrogens may increase the risk of benign (non-cancerous) tumors of the liver.

**FIBROID TUMORS.** Taking estrogens may cause existing fibroid tumors in the uterus to get larger.

**OTHER TUMORS.** Taking estrogens might also cause tumors of the breast, cervix or vagina.

**GALLBLADDER DISEASE.** Estrogens may increase the chance of gallbladder disease.

**HIGH BLOOD PRESSURE.** Estrogens can cause high blood pressure.

## SIDE EFFECTS

Side effects are unwanted effects caused by a drug. Estrogens may cause many side effects, including the following:

1. Vaginal -- bleeding from the vagina (other than your usual monthly period), a change in the amount of menstrual bleeding, missed menstrual period, painful menstrual periods or depression and bloating similar to pre-menstrual depression and bloating, fungus or yeast infection of the vagina (itching or change in mucous), pain or burning feeling during urination.
2. Breast -- enlargement or tenderness, leaking fluids from the breasts.
3. Stomach and intestines -- nausea, vomiting, cramps or pain in the stomach.
4. Skin -- temporary or permanent brown spots on the skin, skin rash, loss of hair from the head or increase in amount of hair on the body.
5. Head and eyes -- headaches, including migraines or dizziness, change in vision, problems with wearing contact lenses.
6. Miscellaneous -- increase or decrease in weight, uncontrollable jerking motions of the body, change in desire for sex (increase or decrease).

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5-2-2

## ESTROGENS

(S-trow-gens)

Estrogens are hormones commonly prescribed to treat symptoms of the menopause. Like all drugs, estrogens have both benefits and risks. These risks and benefits should be considered before deciding to take the drug. Some important information about estrogens is provided by this leaflet. It should be read and put aside for future reference.

First the basic facts about estrogen are summarized. Then more detailed information is given about what estrogens are, why people use them, and how they should be used. The last part of the leaflet discusses what precautions to take when using estrogens and what dangers and side effects might occur. If additional information about estrogens is desired, contact your physician or your pharmacist. A more technical leaflet can be obtained from your pharmacist.

### SUMMARY

Estrogens are female hormones which serve to regulate a woman's sexual development and her menstrual cycle.

Estrogens are usually prescribed for uncomfortable vasomotor symptoms of the menopause, such as "hot flashes" and painful changes in the vagina. For symptoms of the menopause, physicians may recommend that women take estrogen on a four week cycle: three weeks on followed by one week off. Generally, they should be taken in as low a dose and for as short a time as possible.

Estrogens are also prescribed to treat certain cancers in women and men, to correct hypogonadism, or to prevent post-partum breast engorgement. Many oral contraceptives also contain estrogens.

While estrogens have important uses, they can cause serious health problems and many side effects. Estrogens should not be taken by

pregnant women. Nursing mothers, and women who have had liver problems, a stroke, heart attack or angina pectoris, who have a family history of breast cancer, or who have had abnormal vaginal bleeding should discuss these problems with their physician before taking estrogens.

Estrogens may increase the risk of: endometrial cancer, liver tumors, abnormal blood clotting, gallbladder disease, and growth of benign tumors. These dangers should be discussed with your physician before deciding to take estrogens.

### WHAT ESTROGENS ARE

Estrogens are female hormones which are produced by the ovaries and which regulate a woman's menstrual cycle throughout her life.

### USES OF ESTROGENS

**TO RELIEVE SYMPTOMS OF THE MENOPAUSE.** There are two kinds of menopause: "natural" and "surgical." Natural menopause usually occurs between the ages of 45 and 55, while surgical menopause occurs when the ovaries have been removed before the onset of natural menopause.

Menopause is sometimes accompanied by uncomfortable "vasomotor" symptoms: "hot flashes" or "hot flushes," sudden feelings of hotness and sweating, or changes in the vagina (atrophic vaginitis). These symptoms can be relieved by estrogens.

Estrogens cannot relieve all of the symptoms of menopause. For example, estrogens will not relieve nervousness or depression, nor will they make a woman feel young or keep her skin soft. In fact, estrogens cause some women to become depressed.

**TO PREVENT POST-PARTUM BREAST ENGORGEMENT.** Pregnant women not planning to breast-feed their child are sometimes prescribed estrogens immediately after delivery to prevent their breasts from swelling. However, the dosage necessary to reduce swelling is large and the therapy is sometimes

ineffective. In addition, milk-filled breasts usually cause only minor discomfort and may be controlled in other ways.

**TO TREAT HYPOGONADISM.** Estrogens have also been used to correct "hypogonadism," a condition in which a girl's sex organs do not develop normally.

**OTHER USES OF ESTROGENS.** Estrogens are also used to treat some cancers and a certain bone disease called osteoporosis. Some oral contraceptives also contain estrogens.

### HOW TO USE ESTROGENS

Taken for menopausal symptoms, estrogens are low-dose, short-term drugs which are generally administered in four week cycles: three weeks on, one week off. Some doctors recommend that the dosage should be decreased or discontinued every three to six months. In general, estrogens should be used in as small a dose as possible for as short a time as possible.

When taking estrogens for a long time, you should be examined semi-annually to determine if the estrogens should be discontinued.

If you are taking estrogens to treat cancer or for some reason other than menopausal discomfort, your physician will tell you how much to take and how often to take it.

### PRECAUTIONS

Estrogens are powerful drugs and should not be taken unless there is a serious need and no viable alternative. The risks and benefits of estrogens should be discussed with your physician before deciding to take them. Estrogens should not be taken by pregnant women. Nursing mothers and women who have had liver problems should discuss the risks of taking estrogens with their physicians.

Taken while a woman is pregnant, estrogens can seriously damage the fetus. It has been reported that females exposed in utero to diethylstilbestrol (DES) may have an increased

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risk of developing a form of vaginal or cervical cancer in later life. Several reports suggest an association between fetal exposure to estrogens and congenital anomalies, including heart and limb defects. If you are currently taking the drug and think that you are pregnant, discontinue the estrogens immediately and consult your physician.

As a general principle, estrogens should not be administered to nursing mothers since the drug is excreted in human milk and it is not known whether estrogens might harm the child.

Discuss your medical history with your physician before deciding to take estrogens. This is especially important if you have any of the following problems.

Patients with a past history of liver dysfunction have an increased risk of the recurrence of these problems while receiving estrogens. Signs of liver problems include: itching, light-colored bowel movements, dark urine, gastrointestinal discomfort, or jaundice. If you have ever experienced any of these symptoms, contact your physician immediately and discontinue taking estrogens.

If you have had a stroke or heart attack, or angina pectoris, estrogens can increase the likelihood of a recurrence of these illnesses.

Estrogens might speed up the development of breast cancer. Women who have a family history of breast cancer, breast nodules, fibrocystic disease or abnormal mammograms, should discuss this with their physician before deciding to take estrogens. Also, monthly breast self-examinations are recommended. Finally, all women should notify their physician if they notice any changes in their breasts.

Estrogens can complicate certain other medical conditions, including: bone disease, blood clots, abnormal vaginal bleeding, epilepsy, migraine headaches, high levels of calcium in the blood, or problems with the kidneys. If you now have or are prone to these medical conditions, inform your physician before deciding to use estrogens.

Finally, certain medical procedures are affected by estrogens. If you are to undergo lab

tests or surgery requiring extensive bed rest, notify your physician that you are using estrogens.

This drug is to be administered only to the person for whom it was prescribed. It should not be given to anyone else. Estrogens and all medications should be kept where children cannot reach them.

### DANGERS OF ESTROGENS

Estrogens can cause several serious health problems. Discuss these possible problems with your physician before deciding to take estrogens. While you are taking estrogens, any symptoms of the following health problems should be reported to your physician.

**ENDOMETRIAL CANCER.** Estrogens increase the incidence of endometrial carcinoma (cancer of the lining of the uterus). Cyclic administration (three weeks on, one week off) of low doses of estrogen may carry less risk than continuous administration of the drug. Large or prolonged doses of estrogens will increase the risk of cancer. If undiagnosed, persistent, or recurring abnormal vaginal bleeding occurs, you may have endometrial cancer. Note: After a hysterectomy (removal of the uterus) there is no danger of endometrial cancer.

**STROKE, HEART ATTACK, AND BLOOD CLOTS.** Estrogens might increase the risk of a stroke, a heart attack, or a pulmonary embolism (a blood clot that travels to the lungs). Pain in the calves or chest, shortness of breath, dizziness, headaches, changes in vision, or coughing blood, are all symptoms of an embolism.

**LIVER TUMORS.** Benign hepatic tumors appear to be associated with estrogen use.

**FIBROID TUMORS.** Estrogens may cause existing fibroid tumors in the uterus to get larger.

**OTHER TUMORS.** Estrogens might also cause tumors of the breast, cervix, or vagina.

**GALLBLADDER DISEASE.** Estrogens may increase the chance of gallbladder disease in women.

**HIGH BLOOD PRESSURE.** Increased blood pressure may be observed in patients using estrogens.

### SIDE EFFECTS

Side effects are unwanted effects caused by a drug. Estrogens may cause many side effects, including the following:

1. **Vaginal** -- bleeding from the vagina (other than your usual monthly period), a change in the amount of menstrual bleeding, missed menstrual period, painful menstrual periods or depression and bloating similar to pre-menstrual depression and bloating, fungus or yeast infection of the vagina (itching or change in mucous), pain or burning feeling during urination.
2. **Breast** -- enlargement or tenderness, leaking fluids from the breasts.
3. **Stomach and intestines** -- nausea, vomiting, cramps or pain in the stomach.
4. **Skin** -- temporary or permanent brown spots on the skin, skin rash, loss of hair from the head or increase in amount of hair on the body.
5. **Head and eyes** -- headaches, including migraines or dizziness, change in vision, problems with wearing contact lenses.
6. **Miscellaneous** -- increase or decrease in weight, uncontrollable jerking motions of the body, change in desire for sex (increase or decrease).

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S-3.3

## ESTROGENS

### (S-trow-gens)

Estrogens are hormones used to treat symptoms of the menopause. Like all drugs, they have risks. You should understand these risks before deciding to take estrogens. This leaflet contains important information about estrogens and your health. Read it and save it for future reference.

The first part of the leaflet summarizes the basic facts about estrogens. Later parts of the leaflet give more detailed information about what precautions to take when using estrogens and what dangers and side effects might occur. The last part of the leaflet tells you what estrogens are, why people use them, and how to use them. If you would like additional information about estrogens, contact your doctor or your pharmacist. Your pharmacist can give you a more technical leaflet to read.

#### SUMMARY

Estrogens have important uses but can cause serious health problems and many side effects. **Pregnant women should never take estrogens. Nursing mothers, and women who have had liver problems, a stroke, heart attack or angina pectoris should discuss these problems with their doctor before taking estrogens. Women who have a family history of breast cancer, or who have had abnormal vaginal bleeding should also discuss this with their doctor before taking estrogens.**

**Estrogens may increase the risk of endometrial cancer, liver tumors, abnormal blood clotting, gallbladder disease, and growth of non-cancerous tumors.** Discuss these things with your doctor before deciding to take estrogens.

Estrogens are female hormones. They help regulate a woman's sexual development and menstrual cycle.

Doctors usually prescribe estrogens to treat uncomfortable symptoms of the menopause, such as "hot flashes" and painful changes in the vagina. For symptoms of the menopause, your doctor may recommend that you take estrogens on a four week cycle, three weeks on the estrogens followed by one week off. In general, take the lowest dose of estrogens possible for as short a time as possible.

Doctors also use estrogens to treat certain cancers in women and men, to speed up abnormally slow sexual development, or to prevent post-partum breast engorgement. Birth control pills also contain estrogens.

#### PRECAUTIONS

**Estrogens are powerful drugs. Don't take them unless you have a serious need for them and there is no other treatment.** Discuss the risks and benefits of estrogens with your doctor before deciding to take them. In addition, pregnant women should never take estrogens. Nursing mothers and women who have had liver problems should discuss the risks of taking estrogens with their doctors.

**If you take estrogens while you are pregnant, it could seriously damage your child.** Female children whose mothers have taken a certain kind of estrogen (diethylstilbestrol) during pregnancy have a higher risk of getting vaginal and cervical cancer later in life. It could give your child heart defects or abnormally small arms or legs. **If you are pregnant and you have already taken some estrogens, stop taking the estrogens immediately and consult your doctor.**

If you are nursing, estrogens can get into your milk and pass to your child. It is not known whether estrogens might hurt your child.

Discuss your medical history with your doctor before deciding to take estrogens. This is especially important if you have any of the following problems.

**If you have ever had hepatitis, cirrhosis of the liver, or other liver problems, do not take estrogens.** Signs of liver problems include itching, light-colored bowel movements, dark

urine, stomach pain or yellowing of the skin or eyes. If you have ever had any of these symptoms, call your doctor immediately and do not take estrogens.

**If you have had a stroke or a heart attack or if you have angina pectoris, estrogens might increase your chance of having another attack.**

**Estrogens might speed up the development of breast cancer.** If you or other women in your family have had breast cancer, breast lumps, fibrocystic disease or abnormal mammograms, discuss this with your doctor before deciding to take estrogens. Also, do monthly breast examinations on yourself and tell your doctor if you notice any changes in your breasts.

**If you have certain other medical conditions, taking estrogens might make them worse.** These include: bone disease, blood clots, abnormal vaginal bleeding, epilepsy, migraine headaches, high levels of calcium in your blood, or problems with your kidneys. If you have any of these medical conditions, discuss them with your doctor before deciding to take estrogens.

Finally, if you plan to have certain medical procedures, make sure your doctor knows you are taking estrogens. **If you plan to have surgery that requires you to remain in bed for a long time or if you plan to have any lab tests, tell your doctor that you are using estrogens.**

**This drug is for you only. Do not give it to anyone else. Keep estrogens and all medicines where children cannot reach them.**

#### DANGERS OF ESTROGENS

Estrogens can cause several serious health problems. Discuss these possible problems with your doctor before deciding to take estrogens. If you are already taking estrogens and have any symptoms of the following health problems, call your doctor.

**ENDOMETRIAL CANCER.** Taking estrogens increases your chance of getting en-

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**endometrial cancer** (cancer of the lining of the uterus). If you take estrogens continuously, your risk will be greater than if you take it in cycles (three weeks on, one week off). If you take large doses of estrogens or if you take it for a long time you will face a greater risk of cancer. If you have abnormal bleeding from your vagina, you may have endometrial cancer. Note: If you have had your uterus removed (hysterectomy) there is no danger of endometrial cancer.

**STROKE, HEART ATTACK, and BLOOD CLOTS.** Taking estrogens might increase the risk of a stroke, a heart attack, or a blood clot. If you have pain in your calves or chest, shortness of breath, dizziness, headaches, or changes in vision, or if you start coughing blood, you may have a blood clot.

**LIVER TUMORS.** Taking estrogens may increase the risk of benign (non-cancerous) tumors of the liver.

**FIBROID TUMORS.** Taking estrogens may cause existing fibroid tumors in the uterus to get larger.

**OTHER TUMORS.** Taking estrogens might also cause tumors of the breast, cervix or vagina.

**GALLBLADDER DISEASE.** Estrogens may increase the chance of gallbladder disease.

**HIGH BLOOD PRESSURE.** Estrogens can cause high blood pressure.

## SIDE EFFECTS

Side effects are unwanted effects caused by a drug. Estrogens may cause many side effects, including the following:

1. Vaginal -- bleeding from the vagina (other than your usual monthly period), a change in the amount of menstrual bleeding, missed menstrual period, painful menstrual periods or depression and bloating similar to pre-menstrual depression and bloating, fungus or yeast infection of the vagina (itching or change in mucous), pain or burning feeling during urination.

2. Breast -- enlargement or tenderness, leaking fluids from the breasts.

3. Stomach and intestines -- nausea, vomiting, cramps or pain in the stomach.

4. Skin -- temporary or permanent brown spots on the skin, skin rash, loss of hair from the head or increase in amount of hair on the body.

5. Head and eyes -- headaches, including migraines or dizziness, change in vision, problems with wearing contact lenses.

6. Miscellaneous -- increase or decrease in weight, uncontrollable jerking motions of the body, change in desire for sex (increase or decrease).

## WHAT ESTROGENS ARE

Estrogens are female hormones produced by the ovaries. They regulate a woman's menstrual cycle throughout her life.

## USES OF ESTROGENS

**TO RELIEVE SYMPTOMS OF THE MENOPAUSE.** There are two kinds of menopause: "natural" menopause and "surgical" menopause. Natural menopause usually occurs between the ages of 45 and 55. Surgical menopause occurs if a doctor removes a woman's ovaries before the natural menopause occurs.

During menopause, you may have some uncomfortable "vasomotor" symptoms. You may have "hot flashes" or "hot flushes." You may suddenly feel hot and sweaty all over your body. You may develop changes in your vagina (called atrophic vaginitis). Estrogens can relieve these symptoms.

Estrogens cannot relieve all of the symptoms of menopause. For example, you may feel nervous or depressed during the menopause. Estrogens will not relieve these symptoms and they will not make you feel young or keep your skin soft. In fact, estrogens cause some women to become depressed.

**TO PREVENT POST-PARTUM BREAST ENGORGEMENT.** If you are pregnant, you may plan not to breast-feed your child. In that case, your doctor may give you estrogens immediately after delivery to prevent your breasts from swelling. However, a large dose is necessary and doesn't always work. In addition, milk-filled breasts usually cause only minor discomfort and you can treat them in other ways.

**TO TREAT HYPOGONADISM.** Sometimes doctors prescribe estrogens to treat "hypogonadism." This is a condition in which a girl's sex organs do not develop normally.

**OTHER USES OF ESTROGENS.** Your doctor may have prescribed estrogens to treat cancer or a certain bone disease called osteoporosis. Many birth control pills also contain estrogens.

## HOW TO USE ESTROGENS

If you are taking estrogens to treat symptoms of the menopause, you should take them on a four week cycle. Take the estrogens for three weeks, skip a week and then begin again. Your doctor may want you to try to stop taking the estrogens or decrease the dosage every three to six months. In general, you should take as little as possible for as short a time as possible.

If you have to take estrogens for a long time, ask your doctor to examine you at least twice a year to see if you can stop taking the estrogens.

If you are taking estrogens to treat cancer or for some other reason, your doctor will tell you how much to take and how often to take it.

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Rockville, Maryland 20857

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complex writing/risk emphasis

E-2-4

## ESTROGENS (S-trow-gens)

Estrogens are hormones commonly prescribed to treat symptoms of the menopause. Like all drugs, estrogens have risks. These risks should be considered before deciding to take the drug. Some important information about estrogens is provided by this leaflet. It should be read and put aside for future reference.

First the basic facts about estrogen are summarized. Then more detailed information is given about what precautions to take when using estrogens and what dangers and side effects might occur. The last part of the leaflet discusses what estrogens are, why people use them, and how they should be used. If additional information about estrogens is desired, contact your physician or your pharmacist. A more technical leaflet can be obtained from your pharmacist.

### SUMMARY

While estrogens have important uses, they can cause serious health problems and many side effects. *Estrogens should not be taken by pregnant women, nursing mothers, and women who have had liver problems, a stroke, heart attack or angina pectoris, who have a family history of breast cancer, or who have had abnormal vaginal bleeding should discuss these problems with their physician before taking estrogens.*

*Estrogens may increase the risk of: endometrial cancer, liver tumors, abnormal blood clotting, gallbladder disease, and growth of benign tumors.* These dangers should be discussed with your physician before deciding to take estrogens.

Estrogens are female hormones which serve to regulate a woman's sexual development and her menstrual cycle.

Estrogens are usually prescribed for uncomfortable vasomotor symptoms of the men-

opause, such as "hot flashes" and painful changes in the vagina. For symptoms of the menopause, physicians may recommend that women take estrogen on a four week cycle: three weeks on followed by one week off. Generally, they should be taken in as low a dose and for as short a time as possible.

Estrogens are also prescribed to treat certain cancers in women and men, to correct hypogonadism, or to prevent post-partum breast engorgement. Many oral contraceptives also contain estrogens.

### PRECAUTIONS

*Estrogens are powerful drugs and should not be taken unless there is a serious need and no viable alternative.* The risks and benefits of estrogens should be discussed with your physician before deciding to take them. Estrogens should not be taken by pregnant women. Nursing mothers and women who have had liver problems should discuss the risks of taking estrogens with their physicians.

*Taken while a woman is pregnant, estrogens can seriously damage the fetus.* It has been reported that females exposed in utero to diethylstilbestrol (DES) may have an increased risk of developing a form of vaginal or cervical cancer in later life. Several reports suggest an association between fetal exposure to estrogens and congenital anomalies, including heart and limb defects. *If you are currently taking the drug and think that you are pregnant, discontinue the estrogens immediately and consult your physician.*

As a general principle, estrogens should not be administered to nursing mothers since the drug is excreted in human milk and it is not known whether estrogens might harm the child.

Discuss your medical history with your physician before deciding to take estrogens. This is especially important if you have any of the following problems.

*Patients with a past history of liver dysfunction have an increased risk of the reoccurrence of these problems while receiving*

*estrogens.* Signs of liver problems include: itching, light-colored bowel movements, dark urine, gastrointestinal discomfort, or jaundice. If you have ever experienced any of these symptoms, contact your physician immediately and discontinue taking estrogens.

*If you have had a stroke or heart attack, or angina pectoris, estrogens can increase the likelihood of a recurrence of these illnesses.*

*Estrogens might speed up the development of breast cancer.* Women who have a family history of breast cancer, breast nodules, fibrocystic disease or abnormal mammograms, should discuss this with their physician before deciding to take estrogens. Also, monthly breast self-examinations are recommended. Finally, all women should notify their physician if they notice any changes in their breasts.

*Estrogens can complicate certain other medical conditions, including: bone disease, blood clots, abnormal vaginal bleeding, epilepsy, migraine headaches, high levels of calcium in the blood, or problems with the kidneys.* If you now have or are prone to these medical conditions, inform your physician before deciding to use estrogens.

Finally, certain medical procedures are affected by estrogens. *If you are to undergo lab tests or surgery requiring extensive bed rest, notify your physician that you are using estrogens.*

*This drug is to be administered only to the person for whom it was prescribed. It should not be given to anyone else. Estrogens and all medications should be kept where children cannot reach them.*

### DANGERS OF ESTROGENS

Estrogens can cause several serious health problems. Discuss these possible problems with your physician before deciding to take estrogens. While you are taking estrogens, any symptoms of the following health problems should be reported to your physician.

**ENDOMETRIAL CANCER.** *Estrogens increase the incidence of endometrial carcinoma (cancer of the lining of the uterus). Cyclic*



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administration (three weeks on, one week off) of low doses of estrogen may carry less risk than continuous administration of the drug. Large or prolonged doses of estrogens will increase the risk of cancer. If undiagnosed, persistent, or recurring abnormal vaginal bleeding occurs, you may have endometrial cancer. Note: After a hysterectomy (removal of the uterus) there is no danger of endometrial cancer.

**STROKE, HEART ATTACK, AND BLOOD CLOTS.** Estrogens might increase the risk of a stroke, a heart attack, or a pulmonary embolism (a blood clot that travels to the lungs). Pain in the calves or chest, shortness of breath, dizziness, headaches, changes in vision, or coughing blood, are all symptoms of an embolism.

**LIVER TUMORS.** Benign hepatic tumors appear to be associated with estrogen use.

**FIBROID TUMORS.** Estrogens may cause existing fibroid tumors in the uterus to get larger.

**OTHER TUMORS.** Estrogens might also cause tumors of the breast, cervix, or vagina.

**GALLBLADDER DISEASE.** Estrogens may increase the chance of gallbladder disease in women.

**HIGH BLOOD PRESSURE.** Increased blood pressure may be observed in patients using estrogens.

#### SIDE EFFECTS

Side effects are unwanted effects caused by a drug. Estrogens may cause many side effects, including the following:

1. Vaginal -- bleeding from the vagina (other than your usual monthly period), a change in the amount of menstrual bleeding, missed menstrual period, painful menstrual periods or depression and bloating similar to pre-menstrual depression and bloating, fungus or yeast infection of the vagina (itching or change in mucous), pain or burning feeling during urination.

2. Breast -- enlargement or tenderness, leaking fluids from the breasts.
3. Stomach and intestines -- nausea, vomiting, cramps or pain in the stomach.
4. Skin -- temporary or permanent brown spots on the skin, skin rash, loss of hair from the head or increase in amount of hair on the body.
5. Head and eyes -- headaches, including migraines or dizziness, change in vision, problems with wearing contact lenses.
6. Miscellaneous -- increase or decrease in weight, uncontrollable jerking motions of the body, change in desire for sex (increase or decrease).

#### WHAT ESTROGENS ARE

Estrogens are female hormones which are produced by the ovaries and which regulate a woman's menstrual cycle throughout her life.

#### USES OF ESTROGENS

**TO RELIEVE SYMPTOMS OF THE MENOPAUSE.** There are two kinds of menopause: "natural" and "surgical." Natural menopause usually occurs between the ages of 45 and 55, while surgical menopause occurs when the ovaries have been removed before the onset of natural menopause.

Menopause is sometimes accompanied by uncomfortable "vasomotor" symptoms: "hot flashes" or "hot flushes," sudden feelings of hotness and sweating, or changes in the vagina (atrophic vaginitis). These symptoms can be relieved by estrogens.

Estrogens cannot relieve all of the symptoms of menopause. For example, estrogens will not relieve nervousness or depression, nor will they make a woman feel young or keep her skin soft. In fact, estrogens cause some women to become depressed.

**TO PREVENT POST-PARTUM BREAST ENGORGEMENT.** Pregnant women not planning to breast-feed their child are sometimes prescribed estrogens immediately after delivery to prevent their breasts from swelling. However, the dosage necessary to reduce swelling is large and the therapy is sometimes ineffective. In addition, milk-filled breasts usually cause only minor discomfort and may be controlled in other ways.

**TO TREAT HYPOGONADISM.** Estrogens have also been used to correct "hypogonadism," a condition in which a girl's sex organs do not develop normally.

**OTHER USES OF ESTROGENS.** Estrogens are also used to treat some cancers and a certain bone disease called osteoporosis. Some oral contraceptives also contain estrogens.

#### HOW TO USE ESTROGENS

Taken for menopausal symptoms, estrogens are low-dose, short-term drugs which are generally administered in four week cycles: three weeks on, one week off. Some doctors recommend that the dosage should be decreased or discontinued every three to six months. In general, estrogens should be used in as small a dose as possible for as short a time as possible.

When taking estrogens for a long time, you should be examined semi-annually to determine if the estrogens should be discontinued.

If you are taking estrogens to treat cancer or for some reason other than menopausal discomfort, your physician will tell you how much to take and how often to take it.

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S-3-2

# ESTROGENS

## (S-trow-gens)

This leaflet contains important information about estrogens and your health. Read it and save it for future reference. If you would like additional information about estrogens, contact your doctor or pharmacist. Your pharmacist can give you a more technical leaflet.

### USES OF ESTROGENS

**TO RELIEVE SYMPTOMS OF THE MENOPAUSE.** During menopause you may have some uncomfortable "vasomotor" symptoms. You may have "hot flashes" or "hot flushes." You may suddenly feel hot and sweaty all over your body. You may develop changes in your vagina (called atrophic vaginitis). Estrogens can relieve these symptoms.

Estrogens cannot relieve all of the symptoms of menopause. For example, you may feel nervous or depressed during the menopause. Estrogens will not relieve these symptoms and they will not make you feel young or keep your skin soft. In fact, estrogens cause some women to become depressed.

**TO PREVENT POST-PARTUM BREAST ENGORGEMENT.** If you are pregnant, you may plan not to breast-feed your child. In that case, your doctor may give you estrogens

immediately after delivery to prevent your breasts from swelling. However, a large dose is necessary and doesn't always work. In addition, milk-filled breasts usually cause only minor discomfort and you can treat them in other ways.

### HOW TO USE ESTROGENS

If you are taking estrogens to treat symptoms of the menopause you should take them on a four-week cycle. Take the estrogens for three weeks, skip a week and then begin again. Your doctor may want you to try to stop taking the estrogens or decrease the dosage every three to six months. In general, you should take as little as possible for as short a time as possible.

If you have to take estrogens for a long time, ask your doctor to examine you at least twice a year to see if you can stop taking the estrogens.

If you are taking estrogens to treat cancer or for some other reason, your doctor will tell you how much to take and how often to take it.

### PRECAUTIONS

Pregnant women should never take estrogens. If you take estrogens while you are pregnant, it could seriously damage your child.

If you are nursing, estrogens can get into your milk and pass to your child. It is not known whether estrogens might hurt your child.

Discuss your medical history with your doctor before deciding to take estrogens. This is

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especially important if you have any of the following problems.

If you have ever had hepatitis, cirrhosis of the liver, or other liver problems, do not take estrogens. Signs of liver problems include itching, light-colored bowel movements, dark urine, stomach pain or yellowing of the skin or eyes. If you have ever had any of these symptoms, call your doctor immediately and do not take estrogens.

If you have had a stroke or a heart attack or if you have angina pectoris, estrogens might increase your chance of having another attack.

Estrogens might speed up the development of breast cancer. If you or other women in your family have had breast cancer, breast lumps, fibrocystic disease or abnormal mammograms, discuss this with your doctor before deciding to take estrogens.

If you have certain other medical conditions, taking estrogens might make them worse. These include: bone disease, blood clots, abnormal vaginal bleeding, epilepsy, migraine headaches, high levels of calcium in your blood, or problems with your kidneys.

Finally, if you plan to have certain medical procedures, make sure your doctor knows you are taking estrogens. If you plan to have surgery that requires you to remain in bed for a long time or if you plan to have any lab tests, tell your doctor that you are using estrogens.

This drug is for you only. Do not give it to anyone else. Keep estrogens and all medicines where children cannot reach them.

## DANGERS OF ESTROGENS

Estrogens can cause several serious health problems including the following: endometrial cancer, stroke, heart attack, blood clots, liver tumors, fibroid tumors, other tumors, gall-bladder disease, and high blood pressure.

## SIDE EFFECTS

Estrogens may cause many side effects, including the following:

1. **Vaginal** -- bleeding from the vagina (other than your usual monthly period), a change in the amount of menstrual bleeding, missed menstrual periods, pre-menstrual-like bloating, change in the amount of vaginal mucous.
2. **Breast** -- breast tenderness.
3. **Stomach and intestine** -- nausea and vomiting.
4. **Head and eyes** -- headaches (including migraines or dizziness).
5. **Miscellaneous** -- change in desire for sex.

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# ESTROGENS

## (S-trow-gens)

Estrogens are hormones used to treat symptoms of the menopause. Like all drugs, they have both benefits and risks. You should understand both benefits and risks before deciding to take estrogens. This leaflet contains important information about estrogens and your health. Read it and save it for future reference. If you would like additional information about estrogens, contact your doctor or your pharmacist. Your pharmacist can give you a more technical leaflet.

### Estrogens are

- Female hormones
- Produced by ovaries

### Natural function

- To regulate a woman's menstrual cycle throughout life

### Uses

- To relieve symptoms of the menopause
  - Two kinds of menopause:
    - "Natural" menopause (occurs between ages 45 and 55)
    - "Surgical" menopause (surgical removal of ovaries)
  - Relieves "vasomotor" symptoms (hot flashes, sudden sweating, atrophic vaginitis or changes in the vagina)
  - Does NOT relieve nervousness, depression, aging, dry skin

- To prevent post-partum breast engorgement (swelling of breasts in new mothers)
  - Requires large dose
  - Not always effective
  - Discomfort is minor
  - Can treat in other ways
- To treat hypogonadism (abnormal development of a girl's sex organs)
- To treat cancer
- To treat osteoporosis (a bone disease)
- In birth control pills

### Spacing of doses

- For symptoms of menopause, take on four-week cycle - three weeks on, one week off
- For other treatment, your doctor will prescribe dosage and spacing

### How to use estrogens

- Take as little as possible for as short a time as possible
- If you have to take estrogens for a long time ask your doctor to examine you at least twice a year
- Doctor may want you to try to stop taking estrogens or decrease dosage every three to six months

### To avoid problems

- Don't take estrogens unless you have a serious need and there is no other treatment
- Discuss risks and benefits with doctor

### Do not take estrogens if you are pregnant

- Possible risks: vaginal or cervical cancer in female children (caused in the past by diethylstilbestrol), heart defects, abnormally small arms or legs
- Action: stop taking estrogens and consult your doctor

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**Talk to your doctor before taking estrogens if**

- You are nursing
  - Possible risks: estrogens could get into your milk and pass to your child (effects unknown)
- You have had liver problems
  - Symptoms: itching, light-colored bowel movements, dark urine, stomach pain, yellowing of skin or eyes
  - Action: call your doctor and do not take estrogens
- You have had a stroke, heart attack, or angina pectoris
  - Possible risks: another attack
- You have a family history of breast cancer, breast lumps, fibrocystic disease, or abnormal mammograms
  - Action: examine your breasts monthly and tell your doctor about any changes in them
- You have had other medical conditions: bone disease, blood clots, abnormal vaginal bleeding, epilepsy, migraine headaches, high calcium levels in blood, kidney problems
  - Possible risks: medical conditions could become worse
- You plan to have lab tests or surgery requiring you to stay in bed for a long time

**Other precautions:**

- Do not give estrogens to anyone else
- Keep estrogens out of reach of children

**Dangers of estrogens**

- Endometrial cancer (cancer of the lining of the uterus)
  - Risk increased by continuous use, large doses, long-term use
  - Symptoms: abnormal bleeding from the vagina

- Note: if uterus has been removed (hysterectomy), there is no danger of endometrial cancer

- Stroke, heart attack, and blood clots
  - Symptoms: pain in calves or chest, shortness of breath, dizziness, headaches, changes in vision, coughing of blood
- Liver tumors (non-cancerous)
- Fibroid tumors
- Other tumors
- Gallbladder disease
- High blood pressure

**Side effects: unwanted effects caused by a drug**

- Include: bleeding from the vagina (other than your usual monthly period), a change in the amount of menstrual bleeding, missed menstrual period, painful menstrual periods, or depression and bloating similar to pre-menstrual depression and bloating, fungus or yeast infection of the vagina (itching or change in mucous), pain or burning feeling during urination, breast enlargement or tenderness, leaking fluids from the breasts, nausea, vomiting, cramp or pain in the stomach, temporary or permanent brown spots on the skin, skin rash, loss of hair from the head or increase in the amount of hair on the body, headaches, including migraines or dizziness, change in vision, problems with wearing contact lenses, increase or decrease in weight, uncontrollable jerking motions of the body, change in desire for sex (increase or decrease).

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S-3-4

# ESTROGENS

## (S-trow-gens)

This leaflet contains important information about estrogens and your health. Read it and save it for future reference. If you would like additional information about estrogens, contact your doctor or your pharmacist. Your pharmacist can give you a more technical leaflet.

### Uses

- To relieve symptoms of the menopause
  - Relieves "vasomotor" symptoms (hot flashes, sudden sweating, changes in the vagina)
  - Does NOT relieve nervousness, depression, aging, dry skin
- To prevent post-partum breast engorgement (swelling of breasts in new mothers)
  - Requires large dose
  - Not always effective
  - Discomfort is minor
  - Can be treated in other ways

### Spacing of doses

- For symptoms of menopause, take on four-week cycle - three weeks on, one week off
- For other treatment, your doctor will prescribe dosage and spacing

### How to use estrogens

- Take as little as possible for as short a time as possible
- If you have to take estrogens for a long time ask your doctor to examine you at least twice a year
- Doctor may want you to try to stop taking estrogens or decrease dosage every three to six months

### Do not take estrogens if you are pregnant

- Possible risks: could seriously damage child

### Talk to your doctor before taking estrogens if

- You are nursing
  - Possible risks: estrogens could

get into your milk and pass to your child (effects unknown)

- You have had liver problems
  - Symptoms: itching, light-colored bowel movement, dark urine, stomach pain, yellowing of skin or eyes
  - Action: call your doctor and do not take estrogens
- You have had a stroke, heart attack, or angina pectoris
  - Possible risks: another attack
- You have a family history of breast cancer, breast lumps, fibrocystic disease, or abnormal mammograms
- You have had other medical conditions: bone disease, blood clots, abnormal vaginal bleeding, epilepsy, migraine headaches, high calcium levels in blood, kidney problems
  - Possible risks: medical conditions could become worse
- You plan to have lab tests or surgery requiring you to stay in bed for a long time

### Other precautions:

- Do not give estrogens to anyone else
- Keep estrogens out of reach of children

### Dangers of estrogens

- Endometrial cancer
- Stroke, heart attack, and blood clots
- Liver tumors
- Fibroid tumors
- Other tumors
- Gallbladder disease
- High blood pressure

### Side effects

- Include: bleeding from the vagina (other than your usual monthly period), a change in the amount of menstrual bleeding, missed menstrual periods, pre-menstrual-like bloating, change in the amount of vaginal mucus, breast tenderness, nausea or vomiting, headaches (including migraines or dizziness), change in desire for sex

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*explanation/no specific instructions*

R-1-2

# ERYTHROMYCIN

## (e-rith-row-MY-sin)

Erythromycin is an antibiotic used to fight infection. Like all drugs, it has both benefits and risks. You should understand both benefits and risks before taking erythromycin. This leaflet contains important information about erythromycin and your health. Read it and save it for future reference.

The first part of the leaflet summarizes the basic facts about erythromycin. Later parts give more detailed information about the drug, how it works, how to use it, what precautions you should take when using it, and what side effects you might have. If you would like additional information about erythromycin, contact your doctor or your pharmacist. Your pharmacist can give you a more technical leaflet.

### SUMMARY

Erythromycin works against several different bacteria that cause disease. It works mainly by stopping the growth of these bacteria so that the body can kill them.

Try to take erythromycin on an empty stomach at evenly spaced time intervals. Be sure to take the erythromycin exactly as your doctor prescribed until you have taken all of it.

People who are allergic to erythromycin should not take it. People who have liver problems and people who are taking theophylline drugs for asthma should discuss these problems with their doctors before taking erythromycin.

Erythromycin causes very few side effects. But if you have troublesome side effects, call your doctor.

### WHAT ERYTHROMYCIN IS

Erythromycin is an antibiotic used to fight infection. It works against bacteria that cause several different diseases. For example, ery-

thromycin works against upper respiratory infections (such as ear and throat infections), lower respiratory infections (such as pneumonia), and skin and soft tissue infections. Doctors also frequently prescribe erythromycin instead of penicillin for patients who are allergic to penicillin. It does not work against viruses or the common cold.

Drug companies sell erythromycin under different brand names. In addition, erythromycin comes in tablets, capsules, and liquids. It can also be given by injection.

### HOW ERYTHROMYCIN WORKS

Doctors usually prescribe small or medium doses of erythromycin. In this dose, erythromycin stops the growth of the bacteria long enough for the body to kill them. In larger doses, erythromycin can kill bacteria. Usually, however, a smaller dose will cure the infection.

### HOW TO USE ERYTHROMYCIN

Try to take erythromycin on an empty stomach. Take it at least one hour before meals or two hours after meals. That way, more of the erythromycin can get into your bloodstream to fight the infection. You may get an upset stomach when you take the erythromycin this way. If that happens, you may have to take it with a little food. However, it is best to take erythromycin on an empty stomach if you can.

Erythromycin has a bitter taste. So, if you have tablets or capsules, don't chew them. Swallow them whole with water.

Erythromycin also comes in a chewable tablet that tastes better. If you have this kind of tablet, chew the tablet completely before swallowing it.

Try to take the erythromycin at the prescribed time intervals around the clock. If you can't take it around the clock, take your erythromycin at evenly spaced intervals during the time that you are awake. This will keep the amount of erythromycin in your bloodstream at a constantly high level.

If you miss a dose of erythromycin, take it as soon as you think of it. Then take the rest of the day's dose at shorter, but evenly spaced in-

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tervals. Do not take two doses at the same time. But make sure that you take the right number of pills or tablets every day. If you miss two or more doses, take one dose as soon as you remember. Then resume your normal schedule.

Be sure to take the erythromycin exactly as your doctor instructed. Even if you start feeling better, don't stop taking the erythromycin. You might begin to feel better because the drug has stopped the growth of many of the bacteria. However, some of the strongest bacteria may remain alive. If you stop taking the erythromycin, these strong bacteria will grow and multiply. So keep taking the erythromycin until you have taken it all.

If you do not feel much better after taking all of the erythromycin, contact your doctor.

## PRECAUTIONS

The following people should talk to their doctors before taking erythromycin.

If you have ever had an allergic reaction to erythromycin (such as a rash or trouble breathing) do not take it again. If you do, it could cause the same reaction or a more serious one.

If you have had liver trouble in the past, tell your doctor before taking erythromycin. The liver helps remove the drug from your body. So it is important for your liver to be working properly when you take erythromycin. If you have had liver trouble, your doctor may recommend a different antibiotic.

If you have asthma and are taking any medicine containing theophylline, tell your doctor before taking erythromycin. Erythromycin can increase the amount of theophylline in the blood to dangerously high levels. This could cause upset stomach, nausea, vomiting, restlessness, headache, nervousness, insomnia, irritability, confusion or increased heart rate. In order to prevent these symptoms, your doctor may decide to decrease the amount of theophylline you take while you are taking erythromycin.

If you are pregnant or nursing, erythromycin can pass to your child. There is no evidence that the drug will or will not hurt your child.

If, for any reason, your doctor tells you to stop taking erythromycin, throw away any of the drug that is left over. Do not save it or take it for some other infection. If you take it erythromycin when you don't need it, it might not work when you do need it.

This drug is for you only. Do not give it to anyone else. Keep erythromycin and all medicines where children cannot reach them.

## SIDE EFFECTS

Side effects are unwanted effects caused by a drug. Erythromycin usually does not produce any side effects. However, if you have any troublesome side effects, call your doctor. Gastrointestinal problems are the most frequent side effects. These include nausea, vomiting, stomach cramps, and diarrhea. If you have any of these side effects, take your erythromycin with a little food.

Some people have allergic reactions to erythromycin. Usually, these people get mild skin rashes with some itching. Occasionally, people get hives and severe itching. Some people have an allergic reaction that causes them to have trouble breathing. If this happens to you, get emergency help immediately.

If you take erythromycin for a long time, you may get a fungus or yeast infection. Common signs of a yeast infection include mouth sores, or vaginal itching or discharge. If you have any of these signs, call your doctor.

Erythromycin sometimes causes liver damage. Most of the liver damage reported from erythromycin is due to one form of the drug, the estolate salt. The most common brand of this form is called Ilosone. If you have itching, dark urine, continuing fever, stomach pain, nausea, or vomiting, or if your eyes or skin turn yellow, you may have liver damage. If you have any of these symptoms, stop taking the drug and call your doctor.

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no explanation/specific instructions

R-1-3

# ERYTHROMYCIN

## (e-rith-row-MY-sin)

Erythromycin is an antibiotic used to fight infection. Like all drugs, it has both benefits and risks. You should understand both benefits and risks before taking erythromycin. This leaflet contains important information about erythromycin and your health. Read it and save it for future reference.

The first part of the leaflet summarizes the basic facts about erythromycin. Later parts give more detailed information about the drug, how it works, how to use it, what precautions you should take when using it, and what side effects you might have. If you would like additional information about erythromycin, contact your doctor or your pharmacist. Your pharmacist can give you a more technical leaflet.

### SUMMARY

Erythromycin works against several different bacteria that cause disease. It works mainly by stopping the growth of these bacteria so that the body can kill them.

Try to take erythromycin on an empty stomach at evenly spaced time intervals. Be sure to take the erythromycin exactly as your doctor prescribed until you have taken all of it.

People who are allergic to erythromycin should not take it. People who have liver problems and people who are taking theophylline drugs for asthma should discuss these problems with their doctors before taking erythromycin.

Erythromycin causes very few side effects. But if you have troublesome side effects, call your doctor.

### WHAT ERYTHROMYCIN IS

Erythromycin is an antibiotic used to fight infection. It works against bacteria that cause

several different diseases. Doctors also frequently prescribe erythromycin instead of penicillin for patients who are allergic to penicillin. It does not work against viruses or the common cold.

Drug companies sell erythromycin under different brand names. In addition, erythromycin comes in tablets, capsules, and liquids. It can also be given by injection.

### HOW ERYTHROMYCIN WORKS

Doctors usually prescribe small or medium doses of erythromycin. In this dose, erythromycin stops the growth of the bacteria long enough for the body to kill them.

### HOW TO USE ERYTHROMYCIN

Try to take erythromycin on an empty stomach. Take it at least one hour before meals or two hours after meals. You may get an upset stomach when you take the erythromycin this way. If that happens, you may have to take it with a little food. For example, you could take it with a glass of milk. This would relieve the upset stomach. However, it is best to take erythromycin on an empty stomach if you can.

Erythromycin has a bitter taste. So, if you have tablets or capsules, don't chew them. Swallow them whole with water. Try to drink only water with the erythromycin.

Erythromycin also comes in a chewable tablet that tastes better. If you have this kind of tablet, chew the tablet completely before swallowing it.

Try to take the erythromycin at the prescribed time intervals around the clock. For example, if your doctor tells you to take it four times a day, try to take your erythromycin every six hours. If you can't take it around the clock, take your erythromycin at evenly spaced intervals during the time that you are awake. For example, you could take the first tablet when you get up in the morning, the second tablet an hour before your lunch, the third tablet an hour before you eat dinner, and the last tablet right before you go to bed.

R-1-3.

If you miss a dose of erythromycin, take it as soon as you think of it. Then take the rest of the day's dose at shorter, but evenly spaced intervals. For example, you might take the rest of the day's tablets or capsules every three hours instead of every four hours. Do not take two doses at the same time. But make sure that you take the right number of pills or tablets every day. If you miss two or more doses, take one dose as soon as you remember. Then resume your normal schedule.

Be sure to take the erythromycin exactly as your doctor instructed. Take all of the tablets or capsules that came in your prescription. Even if you start feeling better, don't stop taking the erythromycin.

If you do not feel much better after taking all of the erythromycin, contact your doctor. Tell him or her which symptoms are still bothering you.

## PRECAUTIONS

The following people should talk to their doctors before taking erythromycin.

If you have ever had an allergic reaction to erythromycin (such as a rash or trouble breathing) do not take it again. Tell your doctor about your allergy and request a different antibiotic.

If you have had liver trouble in the past, tell your doctor before taking erythromycin.

If you have asthma and are taking any medicine containing theophylline, tell your doctor before taking erythromycin. Taking the two drugs together might cause upset stomach, nausea, vomiting, restlessness, headache, nervousness, insomnia, irritability, confusion, or increased heart rate. If you have any of these symptoms, contact your doctor. Make sure he or she knows you have been taking theophylline.

If you are pregnant or nursing, erythromycin can pass to your child. There is no evidence that the drug will or will not hurt your child.

If, for any reason, your doctor tells you to stop taking erythromycin, throw away any of the

drug that is left over. Do not save it or take it for some other infection.

This drug is for you only. Do not give it to anyone else. Keep erythromycin and all medicines where children cannot reach them. For example, store them on a high shelf or in a locked cupboard.

## SIDE EFFECTS

Side effects are unwanted effects caused by a drug. Erythromycin usually does not produce any side effects. However, if you have any troublesome side effects, call your doctor. Gastrointestinal problems are the most frequent side effects. These include nausea, vomiting, stomach cramps, and diarrhea. If you have any of these side effects, take your erythromycin with a little food.

Some people have allergic reactions to erythromycin. Usually, these people get mild skin rashes with some itching. Occasionally, people get hives and severe itching. Some people have an allergic reaction that causes them to have trouble breathing. If this happens to you, get emergency help immediately. Tell the people who help you that you have been taking erythromycin. If possible, take your prescription container with you.

If you take erythromycin for a long time, you may get a fungus or yeast infection. Common signs of a yeast infection include mouth sores, or vaginal itching or discharge. If you have any of these signs, call your doctor.

Erythromycin sometimes causes liver damage. Most of the liver damage reported from erythromycin is due to one form of the drug, the estolate salt. The most common brand of this form is called Ilosone. If you have itching, dark urine, continuing fever, stomach pain, nausea, or vomiting, or if your eyes or skin turn yellow, you may have liver damage. If you have any of these symptoms, stop taking the drug and call your doctor.

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5600 Fishers Lane  
Rockville, Maryland 20857

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# ERYTHROMYCIN

## (e-rith-row-MY-sin)

Erythromycin is an antibiotic used to fight infection. Like all drugs, it has both benefits and risks. You should understand both benefits and risks before taking erythromycin. This leaflet contains important information about erythromycin and your health. Read it and save it for future reference.

The first part of the leaflet summarizes the basic facts about erythromycin. Later parts give more detailed information about the drug, how it works, how to use it, what precautions you should take when using it, and what side effects you might have. If you would like additional information about erythromycin, contact your doctor or your pharmacist. Your pharmacist can give you a more technical leaflet.

## SUMMARY

Erythromycin works against several different bacteria that cause disease. It works mainly by stopping the growth of these bacteria so that the body can kill them.

Try to take erythromycin on an empty stomach at evenly spaced time intervals. Be sure to take the erythromycin exactly as your doctor prescribed until you have taken all of it.

People who are allergic to erythromycin should not take it. People who have liver problems

and people who are taking theophylline drugs for asthma should discuss these problems with their doctors before taking erythromycin.

Erythromycin causes very few side effects. But if you have troublesome side effects, call your doctor.

## WHAT ERYTHROMYCIN IS

Erythromycin is an antibiotic used to fight infection. It works against bacteria that cause several different diseases. For example, erythromycin works against upper respiratory infections (such as ear and throat infections), lower respiratory infections (such as pneumonia), and skin and soft tissue infections. Doctors also frequently prescribe erythromycin instead of penicillin for patients who are allergic to penicillin. It does not work against viruses or the common cold.

Drug companies sell erythromycin under different brand names. In addition, erythromycin comes in tablets, capsules, and liquids. It can also be given by injection.

## HOW ERYTHROMYCIN WORKS

Doctors usually prescribe small or medium doses of erythromycin. In this dose, erythromycin stops the growth of the bacteria long enough for the body to kill them. In larger doses, erythromycin can kill bacteria. Usually, however, a smaller dose will cure the infection.

## HOW TO USE ERYTHROMYCIN

Try to take erythromycin on an empty stomach. Take it at least one hour before meals or two

hours after meals. That way, more of the erythromycin can get into your bloodstream to fight the infection. You may get an upset stomach when you take the erythromycin this way. If that happens, you may have to take it with a little food. For example, you could take it with a glass of milk. This would relieve the upset stomach. However, it is best to take erythromycin on an empty stomach if you can.

Erythromycin has a bitter taste. So, if you have tablets or capsules, don't chew them. Swallow them whole with water. Try to drink only water with the erythromycin.

Erythromycin also comes in a chewable tablet that tastes better. If you have this kind of tablet, chew the tablet completely before swallowing it.

Try to take the erythromycin at the prescribed time intervals around the clock. For example, if your doctor tells you to take it four times a day, try to take your erythromycin every six hours. If you can't take it around the clock, take your erythromycin at evenly spaced intervals during the time that you are awake. For example, you could take the first tablet when you get up in the morning, the second tablet an hour before your lunch, the third tablet an hour before you eat dinner, and the last tablet right before you go to bed. This will keep the amount of erythromycin in your bloodstream at a constantly high level.

If you miss a dose of erythromycin, take it as soon as you think of it. Then take the rest of the day's dose at shorter, but evenly spaced intervals. For example, you might take the rest of the day's tablets or capsules every three hours instead of every four hours. Do not take two doses at the same time. But make sure that you take the right number of pills or

R-1-4.

tablets every day. If you miss two or more doses, take one dose as soon as you remember. Then resume your normal schedule.

Be sure to take the erythromycin exactly as your doctor instructed. Take all of the tablets or capsules that came in your prescription. Even if you start feeling better, don't stop taking the erythromycin. You might begin to feel better because the drug has stopped the growth of many of the bacteria. However, some of the strongest bacteria may remain alive. If you stop taking the erythromycin, these strong bacteria will grow and multiply. So keep taking the erythromycin until you have taken it all.

If you do not feel much better after taking all of the erythromycin, contact your doctor. Tell him or her which symptoms are still bothering you.

## PRECAUTIONS

The following people should talk to their doctors before taking erythromycin.

If you have ever had an allergic reaction to erythromycin (such as a rash or trouble breathing) do not take it again. If you do, it could cause the same reaction or a more serious one. Tell your doctor about your allergy and request a different antibiotic.

If you have had liver trouble in the past, tell your doctor before taking erythromycin. The liver helps remove the drug from your body. So it is important for your liver to be working properly when you take erythromycin. If you have had liver trouble, your doctor may recommend a different antibiotic.

If you have asthma and are taking any medicine containing theophylline, tell your doctor before taking erythromycin. Erythromycin can increase the amount of theophylline in the blood to dangerously high levels. This could cause upset stomach, nausea, vomiting, restlessness, headache, nervousness, insomnia, irritability, confusion or increased heart rate. In order to prevent these symptoms, your doctor may decide to decrease the amount of theophylline you take while you are taking erythromycin. If you have any of these symptoms, contact your doctor. Make sure he or she knows you have been taking theophylline.

If you are pregnant or nursing, erythromycin can pass to your child. There is no evidence that the drug will or will not hurt your child.

If, for any reason, your doctor tells you to stop taking erythromycin, throw away any of the drug that is left over. Do not save it or take it for some other infection. If you take erythromycin when you don't need it, it might not work when you do need it.

This drug is for you only. Do not give it to anyone else. Keep erythromycin and all medicines where children cannot reach them. For example, store them on a high shelf or in a locked cupboard.

## SIDE EFFECTS

Side effects are unwanted effects caused by a drug. Erythromycin usually does not produce any side effects. However, if you have any troublesome side effects, call your doctor. Gastrointestinal problems are the most frequent side effects. These include nausea, vomiting, stomach cramps, and diarrhea. If

you have any of these side effects, take your erythromycin with a little food.

Some people have allergic reactions to erythromycin. Usually, these people get mild skin rashes with some itching. Occasionally, people get hives and severe itching. Some people have an allergic reaction that causes them to have trouble breathing. If this happens to you, get emergency help immediately. Tell the people who help you that you have been taking erythromycin. If possible, take your prescription container with you.

If you take erythromycin for a long time, you may get a fungus or yeast infection. Common signs of a yeast infection include mouth sores, or vaginal itching or discharge. If you have any of these signs, call your doctor.

Erythromycin sometimes causes liver damage. Most of the liver damage reported from erythromycin is due to one form of the drug, the estolate salt. The most common brand of this form is called Ilosone. If you have itching, dark urine, continuing fever, stomach pain, nausea, or vomiting, or if your eyes or skin turn yellow, you may have liver damage. If you have any of these symptoms, stop taking the drug and call your doctor.

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Core version  
no explanation  
no specific instructions  
simplified writing  
no risk emphasis  
text format  
full content

R 2-1

# ERYTHROMYCIN

(e-rith-row-MY-sin)

Erythromycin is an antibiotic used to fight infection. Like all drugs, it has both benefits and risks. You should understand both benefits and risks before taking erythromycin. This leaflet contains important information about erythromycin and your health. Read it and save it for future reference.

The first part of the leaflet summarizes the basic facts about erythromycin. Later parts give more detailed information about the drug, how it works, how to use it, what precautions you should take when using it, and what side effects you might have. If you would like additional information about erythromycin, contact your doctor or your pharmacist. Your pharmacist can give you a more technical leaflet.

## SUMMARY

Erythromycin works against several different bacteria that cause disease. It works mainly by stopping the growth of these bacteria so that the body can kill them.

Try to take erythromycin on an empty stomach at evenly spaced time intervals. Be sure to take the erythromycin exactly as your doctor prescribed until you have taken all of it.

People who are allergic to erythromycin should not take it. People who have liver problems and people who are taking theophylline drugs for asthma should discuss these problems with their doctors before taking erythromycin.

Erythromycin causes very few side effects. But if you have troublesome side effects, call your doctor..

## WHAT ERYTHROMYCIN IS

Erythromycin is an antibiotic used to fight infection. It works against bacteria that cause several different diseases. Doctors also frequently prescribe erythromycin instead of penicillin for patients who are allergic to penicillin. It does not work against viruses or the common cold.

Drug companies sell erythromycin under different brand names. In addition, erythromycin comes in tablets, capsules, and liquids. It can also be given by injection.

## HOW ERYTHROMYCIN WORKS

Doctors usually prescribe small or medium doses of erythromycin. In this dose, erythromycin stops the growth of the bacteria long enough for the body to kill them.

## HOW TO USE ERYTHROMYCIN

Try to take erythromycin on an empty stomach. Take it at least one hour before meals or two hours after meals. You may get an upset stomach when you take the erythromycin this way. If that happens, you may have to take it with a little food. However, it is best to take erythromycin on an empty stomach if you can.

Erythromycin has a bitter taste. So, if you have tablets or capsules, don't chew them. Swallow them whole with water.

Erythromycin also comes in a chewable tablet that tastes better. If you have this kind of tablet, chew the tablet completely before swallowing it.

Try to take the erythromycin at the prescribed time intervals around the clock. If you can't take it around the clock, take your erythromycin at evenly spaced intervals during the time that you are awake.

R-2-1

If you miss a dose of erythromycin, take it as soon as you think of it. Then take the rest of the day's dose at shorter, but evenly spaced intervals. Do not take two doses at the same time. But make sure that you take the right number of pills or tablets every day. If you miss two or more doses, take one dose as soon as you remember. Then resume your normal schedule.

Be sure to take the erythromycin exactly as your doctor instructed. Even if you start feeling better, don't stop taking the erythromycin until you've taken it all.

## PRECAUTIONS

The following people should talk to their doctors before taking erythromycin.

If you have ever had an allergic reaction to erythromycin (such as a rash or trouble breathing) do not take it again.

If you have had liver trouble in the past, tell your doctor before taking erythromycin.

If you have asthma and are taking any medicine containing theophylline, tell your doctor before taking erythromycin. Taking the two drugs together might cause upset stomach, nausea, vomiting, restlessness, headache, nervousness, insomnia, irritability, confusion, or increased heart rate.

If you are pregnant or nursing, erythromycin can pass to your child. There is no evidence that the drug will or will not hurt your child.

If, for any reason, your doctor tells you to stop taking erythromycin, throw away any of the drug that is left over. Do not save it or take it for some other infection.

This drug is for you only. Do not give it to anyone else. Keep erythromycin and all medicines where children cannot reach them.

## SIDE EFFECTS

Side effects are unwanted effects caused by a drug. Erythromycin usually does not produce any side effects. However, if you have any troublesome side effects, call your doctor. Gastrointestinal problems are the most frequent side effects. These include nausea, vomiting, stomach cramps, and diarrhea. If you have any of these side effects, take your erythromycin with a little food.

Some people have allergic reactions to erythromycin. Usually, these people get mild skin rashes with some itching. Occasionally, people get hives and severe itching. Some people have an allergic reaction that causes them to have trouble breathing. If this happens to you, get emergency help immediately.

If you take erythromycin for a long time, you may get a fungus or yeast infection. Common signs of a yeast infection include mouth sores, or vaginal itching or discharge. If you have any of these signs, call your doctor.

Erythromycin sometimes causes liver damage. Most of the liver damage reported from erythromycin is due to one form of the drug, the estolate salt. The most common brand of this form is called Ilosone. If you have itching, dark urine, continuing fever, stomach pain, nausea, or vomiting, or if your eyes or skin turn yellow, you may have liver damage. If you have any of these symptoms, stop taking the drug and call your doctor.

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Rockville, Maryland 20857

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*complex writing/no risk emphasis*

A-2-2

# ERYTHROMYCIN

(e-rith-row-MY-sin)

Erythromycin is an antibiotic used to fight infection. Like all drugs, erythromycin has both benefits and risks. These benefits and risks should be considered before taking the drug. Some important information about erythromycin and your health is provided by this leaflet. It should be read and put aside for future reference.

First, the basic facts about erythromycin will be summarized. Then more detailed information is given about the drug, how it works, how it should be used, what precautions to take when using it, and what side effects might occur. If additional information about erythromycin is desired, contact your physician or your pharmacist. A more technical leaflet can be obtained from your pharmacist.

## SUMMARY

Erythromycin works against several different bacteria that cause a number of disease conditions. Its main action is to stop the growth of these bacteria so that the body can eliminate them.

Erythromycin should be taken on an empty stomach at evenly spaced time intervals. Erythromycin should be taken exactly as your physician prescribed until you have taken all of it.

Erythromycin should not be taken by those who have had a previous allergic reaction to it. People who have liver problems or people who are taking theophylline drugs for asthma should discuss these problems with their physicians before taking erythromycin.

Very few side effects are caused by erythromycin. But if troublesome side effects occur, call your physician.

## WHAT ERYTHROMYCIN IS

Erythromycin, which is an antibiotic, works against many of the infectious microorganisms (bacteria) that cause several different disease conditions in patients. Erythromycin is also used for treatment of infections when a patient is allergic to penicillin. Erythromycin is ineffective against non-bacterial conditions such as virus or the common cold.

Since it is manufactured and distributed by various pharmaceutical companies, the drug is available under many different trade names. It may appear in tablet, capsule, or liquid form, and can also be administered by injection.

## HOW ERYTHROMYCIN WORKS

Physicians usually prescribe small or medium doses of erythromycin, which stop the growth of the bacteria long enough for the body to eliminate them.

## HOW TO USE ERYTHROMYCIN

Erythromycin is best absorbed on an empty stomach. It should be taken at least one hour before or two hours after meals. Taken this way, erythromycin can sometimes cause gastrointestinal distress. If that happens, it can be taken with a small amount of food. However, it is best to take erythromycin on an empty stomach if possible.

Erythromycin tablets have a bitter taste, and should be swallowed whole with water, and not chewed.

Erythromycin is also available as a chewable tablet. In this dosage form, the tablet should be chewed completely before being swallowed.

R-2-2

It is best to take this medication at the prescribed time intervals around the clock. However, if this is impossible, erythromycin should be taken at evenly spaced time intervals during waking hours.

If you miss a dose of erythromycin, take it as soon as you think of it. Then take the rest of the day's dose at shorter, but evenly spaced intervals. Two doses should not be taken at the same time. However, it is essential to take the prescribed dosage every day. When two or more doses are missed, take only one dose as soon as you remember and then resume your normal schedule.

Erythromycin, like all drugs, should be taken exactly as directed. Even if symptoms improve, the drug should not be stopped until all the tablets or capsules in the prescription have been used up.

## PRECAUTIONS

The following people should talk to their physicians before taking erythromycin.

People hypersensitive to erythromycin should not take the drug.

If you have had liver trouble in the past, tell your physician before taking erythromycin.

If you have asthma and are taking any medicine containing theophylline, tell your physician before taking erythromycin. Taking the two drugs together might cause upset stomach, nausea, vomiting, restlessness, headache, nervousness, insomnia, irritability, confusion, or increased heart rate.

If you are pregnant or nursing, erythromycin can pass from the mother to the child. Available evidence does not indicate whether or not erythromycin harms the fetus or nursing child.

Any unused medication remaining in this prescription should be discarded after your

physician discontinues it. It should not be saved for use for another infection.

This drug is to be administered only to the person for whom it has been prescribed. It should not be given to anyone else. Erythromycin and all medications should be kept where children cannot reach them.

## SIDE EFFECTS

Side effects are unwanted effects caused by a drug. Erythromycin infrequently produces side effects. However, if any troublesome side effects occur, contact a physician. The most frequently occurring reactions are related to gastrointestinal distress, including nausea, vomiting, stomach cramps, and diarrhea. Erythromycin may have to be taken with small amounts of food to avoid these side effects.

Allergic reactions including mild skin rashes with some itching have occurred in some people. Occasionally, people get hives and severe itching. Rarely have serious anaphylactic allergic reactions (involving serious breathing difficulty) been reported. If this reaction occurs, get emergency help immediately.

Taking erythromycin for a prolonged amount of time sometimes causes a fungal or yeast infection. Mouth sores, and vaginal itching or discharge are the common symptoms of yeast infection. If they occur, call your physician.

Damage to the liver has sometimes been observed primarily with the estolate salt of erythromycin. The most common brand of this form is Ilosone. Signs of liver damage may be recognized by itching, dark urine, continuing fever, abdominal discomfort, nausea or vomiting, or jaundice. If you observe any of these symptoms, discontinue use of the drug and contact your physician.

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*simplified writing/risk emphasis*

A-2-3

# ERYTHROMYCIN

## (e-rith-row-MY-sin)

Erythromycin is an antibiotic used to fight infection. Like all drugs, it has risks. You should understand these risks before taking erythromycin. This leaflet contains important information about erythromycin and your health. Read it and save it for future reference.

The first part of the leaflet summarizes the basic facts about erythromycin. Later parts give more detailed information about what precautions to take when using erythromycin, what side effects might occur, how erythromycin should be used, how it works, and what it is. If you would like additional information about erythromycin, contact your doctor or your pharmacist. Your pharmacist can give you a more technical leaflet.

### SUMMARY

*People who are allergic to erythromycin should not take it. People who have liver problems and people who are taking theophylline drugs for asthma should discuss these problems with their doctors before taking erythromycin.*

Erythromycin causes very few side effects. *But if you have troublesome side effects, call your doctor.*

Erythromycin works against several different bacteria that cause disease. It works mainly by stopping the growth of these bacteria so that the body can kill them.

Try to take erythromycin on an empty stomach at evenly spaced time intervals. Be sure to take the erythromycin exactly as your doctor prescribed until you have taken all of it.

### PRECAUTIONS

The following people should talk to their doctors before taking erythromycin.

*If you have ever had an allergic reaction to erythromycin (such as a rash or trouble breathing) do not take it again.*

*If you have had liver trouble in the past, tell your doctor before taking erythromycin.*

*If you have asthma and are taking any medicine containing theophylline, tell your doctor before taking erythromycin. Taking the two drugs together might cause upset stomach, nausea, vomiting, restlessness, headache, nervousness, insomnia, irritability, confusion, or increased heart rate.*

*If you are pregnant or nursing, erythromycin can pass to your child. There is no evidence that the drug will or will not hurt your child.*

If for any reason, your doctor tells you to stop taking erythromycin, throw away any of the drug that is left over. *Do not save it or take it for some other infection.*

This drug is for you only. *Do not give it to anyone else. Keep erythromycin and all medicines where children cannot reach them.*

### SIDE EFFECTS

Side effects are unwanted effects caused by a drug. Erythromycin usually does not produce any side effects. However, if you have any troublesome side effects, call your doctor. *Gastrointestinal problems are the most frequent side effects.* These include nausea, vomiting, stomach cramps, and diarrhea. If you have any of these side effects, take your erythromycin with a little food.

Some people have allergic reactions to erythromycin. Usually, these people get mild skin rashes with some itching. Occasionally, people get hives and severe itching. *Some people*

R-2-3

*have an allergic reaction that causes them to have trouble breathing. If this happens to you, get emergency help immediately.*

*If you take erythromycin for a long time, you may get a fungus or yeast infection. Common signs of a yeast infection include mouth sores, or vaginal itching or discharge. If you have any of these signs, call your doctor.*

*Erythromycin sometimes causes liver damage. Most of the liver damage reported from erythromycin is due to one form of the drug, the estolate salt. The most common brand of this form is called Ilosone. If you have itching, dark urine, continuing fever, stomach pain, nausea, or vomiting, or if your eyes or skin turn yellow, you may have liver damage. If you have any of these symptoms, stop taking the drug and call your doctor.*

## HOW TO USE ERYTHROMYCIN

Try to take erythromycin on an empty stomach. Take it at least one hour before meals or two hours after meals. You may get an upset stomach when you take the erythromycin this way. If that happens, you may have to take it with a little food. However, it is best to take erythromycin on an empty stomach if you can.

Erythromycin has a bitter taste. So, if you have tablets or capsules, don't chew them. Swallow them whole with water.

Erythromycin also comes in a chewable tablet that tastes better. If you have this kind of tablet, chew the tablet completely before swallowing it.

Try to take the erythromycin at the prescribed time intervals around the clock. If you can't take it around the clock, take your erythromycin at evenly spaced intervals during the time that you are awake.

If you miss a dose of erythromycin, take it as soon as you think of it. Then take the rest of the day's dose at shorter, but evenly spaced in-

tervals. Do not take two doses at the same time. But make sure that you take the right number of pills or tablets every day. If you miss two or more doses, take one dose as soon as you remember. Then resume your normal schedule.

Be sure to take the erythromycin exactly as your doctor instructed. Even if you start feeling better, don't stop taking the erythromycin until you've taken it all.

## HOW ERYTHROMYCIN WORKS

Doctors usually prescribe small or medium doses of erythromycin. In this dose, erythromycin stops the growth of the bacteria long enough for the body to kill them.

## WHAT ERYTHROMYCIN IS

Erythromycin is an antibiotic used to fight infection. It works against bacteria that cause several different diseases. Doctors also frequently prescribe erythromycin instead of penicillin for patients who are allergic to penicillin. It does not work against viruses or the common cold.

Drug companies sell erythromycin under different brand names. In addition, erythromycin comes in tablets, capsules, and liquids. It can also be given by injection.

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Rockville, Maryland 20857

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R-2-4

# ERYTHROMYCIN

(e-rith-row-MY-sin)

Erythromycin is an antibiotic used to fight infection. Like all drugs, erythromycin has risks. These risks should be considered before taking the drug. Some important information about erythromycin and your health is provided by this leaflet. It should be read and put aside for future reference.

First, the basic facts about erythromycin will be summarized. Then more detailed information is given about what precautions to take when using erythromycin, what side effects might occur, what erythromycin is, how it works, and how it should be used. If additional information about erythromycin is desired, contact your physician or your pharmacist. A more technical leaflet can be obtained from your pharmacist.

## SUMMARY

*Erythromycin should not be taken by those who have had a previous allergic reaction to it. People who have liver problems or people who are taking theophylline drugs for asthma should discuss these problems with their physicians before taking erythromycin.*

Very few side effects are caused by erythromycin. *But if troublesome side effects occur, call your physician.*

Erythromycin works against several different bacteria that cause a number of disease conditions. Its main action is to stop the growth of these bacteria so that the body can eliminate them.

Erythromycin should be taken on an empty stomach at evenly spaced time intervals. Erythromycin should be taken exactly as your physician prescribed until you have taken all of it.

## PRECAUTIONS

The following people should talk to their physicians before taking erythromycin.

*People hypersensitive to erythromycin should not take the drug.*

*If you have had liver trouble in the past, tell your physician before taking erythromycin.*

*If you have asthma and are taking any medicine containing theophylline, tell your physician before taking erythromycin. Taking the two drugs together might cause upset stomach, nausea, vomiting, restlessness, headache, nervousness, insomnia, irritability, confusion, or increased heart rate.*

*If you are pregnant or nursing, erythromycin can pass from the mother to the child. Available evidence does not indicate whether or not erythromycin harms the fetus or nursing child.*

Any unused medication remaining in this prescription should be discarded after your physician discontinues it. *It should not be saved for use for another infection.*

This drug is to be administered only to the person for whom it has been prescribed. *It should not be given to anyone else. Erythromycin and all medications should be kept where children cannot reach them.*

## SIDE EFFECTS

Side effects are unwanted effects caused by a drug. Erythromycin infrequently produces side effects. However, if any troublesome side effects occur, contact a physician. *The most frequently occurring reactions are related to gastrointestinal distress, including nausea, vomiting, stomach cramps, and diarrhea. Erythromycin may have to be taken with small amounts of food to avoid these side effects.*

Allergic reactions including mild skin rashes with some itching have occurred in some people. Occasionally, people get hives and severe itching. *Rarely have serious ana-*

R-24

*phylactic allergic reactions (involving serious breathing difficulty) been reported. If this reaction occurs, get emergency help immediately.*

*Taking erythromycin for a prolonged amount of time may cause an overgrowth of susceptible bacteria and lead to a fungal or yeast infection. Mouth sores, and vaginal itching or discharge are the common symptoms of yeast infection. If they occur, call your physician.*

*Damage to the liver has sometimes been observed primarily with the estolate salt of erythromycin. The most common brand of this form is Ilosone. Signs of liver damage may be recognized by itching, dark urine, continuing fever, abdominal discomfort, nausea or vomiting, or jaundice. If you observe any of these symptoms, discontinue use of the drug and contact your physician.*

## WHAT ERYTHROMYCIN IS

Erythromycin, which is an antibiotic, works against many of the infectious microorganisms (bacteria) that cause several different disease conditions in patients. Erythromycin is also used for treatment of infections when a patient is allergic to penicillin. Erythromycin is ineffective against non-bacterial conditions such as virus or the common cold.

Since it is manufactured and distributed by various pharmaceutical companies, the drug is available under many different trade names. It may appear in tablet, capsule, or liquid form, and can also be administered by injection.

## HOW ERYTHROMYCIN WORKS

Physicians usually prescribe small or medium doses of erythromycin, which stops the growth of the bacteria long enough for the body to eliminate them.

## HOW TO USE ERYTHROMYCIN

Erythromycin is best absorbed on an empty stomach. It should be taken at least one hour

before or two hours after meals. Taken this way, erythromycin can sometimes cause gastrointestinal distress. If that happens, it can be taken with a small amount of food. However, it is best to take erythromycin on an empty stomach if possible.

Erythromycin tablets have a bitter taste, and should be swallowed whole with water, and not chewed.

Erythromycin is also available as a chewable tablet. In this dosage form, the tablet should be chewed completely before being swallowed.

It is best to take this medication at the prescribed time intervals around the clock. However, if this is impossible, erythromycin should be taken at evenly spaced time intervals during waking hours.

If you miss a dose of erythromycin, take it as soon as you think of it. Then take the rest of the day's dose at shorter, but evenly spaced intervals. Two doses should not be taken at the same time. However, it is essential to take the prescribed dosage every day. When two or more doses are missed, take only one dose as soon as you remember and then resume your normal schedule.

Erythromycin, like all drugs, should be taken exactly as directed. Even if symptoms improve, the drug should not be stopped until all the tablets or capsules in the prescription have been used up.

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5600 Fishers Lane  
Rockville, Maryland 20857

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reduced content/text format

A-3-2

## ERYTHROMYCIN

### (e-rith-row-MY-sin)

This leaflet contains important information about erythromycin and your health. Read it and save it for future reference. If you would like additional information about erythromycin, contact your doctor or pharmacist. Your pharmacist can give you a more technical leaflet.

#### WHAT ERYTHROMYCIN IS

Erythromycin is an antibiotic used to fight infection. It works against bacteria that cause several different diseases. Doctors also frequently prescribe erythromycin instead of penicillin for patients who are allergic to penicillin. It does not work against viruses or the common cold.

Drug companies sell erythromycin under different brand names. In addition, erythromycin comes in tablets, capsules, and liquids. It can also be given by injection.

#### HOW TO USE ERYTHROMYCIN

Try to take erythromycin on an empty stomach. Take it at least one hour before meals or two hours after meals. Swallow the tablets or capsules whole with water.

Try to take the erythromycin at the prescribed time intervals around the clock.

If you miss a dose of erythromycin, take it as soon as you think of it.

Be sure to take the erythromycin exactly as your doctor instructed. Even if you start feeling better, don't stop taking the erythromycin until you've taken it all.

#### PRECAUTIONS

The following people should talk to their doctors before taking erythromycin.

If you have ever had an allergic reaction to erythromycin (such as a rash or trouble breathing) do not take it again.

If you have had liver trouble in the past, tell your doctor before taking erythromycin.

If you have asthma and are taking any medicine containing theophylline, tell your doctor before taking erythromycin.

If you are pregnant or nursing, erythromycin can pass to your child. There is no evidence that the drug will or will not hurt your child.

If, for any reason, your doctor tells you to stop taking erythromycin, throw away any of the drug that is left over. Do not save it or take it for some other infection.

This drug is for you only. Do not give it to anyone else. Keep erythromycin and all medicines where children cannot reach them.

#### SIDE EFFECTS

Side effects are unwanted effects caused by a drug. Erythromycin usually does not produce any side effects. However, if you have any troublesome side effects, call your doctor. Gastrointestinal problems are the most frequent side effects. These include nausea, vomiting, stomach cramps, and diarrhea. If you have any of these side effects, take your erythromycin with a little food.

Some people have allergic reactions to erythromycin. This ranges from a mild skin rash to trouble breathing. If this happens to you, get emergency help immediately.

If you take erythromycin for a long time, you may get a fungus or yeast infection. Common signs of a yeast infection include mouth sores, or vaginal itching or discharge. If you have any of these signs, call your doctor.

Erythromycin sometimes causes liver damage. Most of the liver damage reported from erythromycin is due to one form of the drug, the estolate salt. The most common brand of this form is called Ilosone. If you have itching, dark urine, continuing fever, stomach pain, nausea or vomiting, or if your eyes or skin turn yellow, you may have liver damage. If you have any of these symptoms, stop taking the drug and call your doctor.

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5600 Fishers Lane  
Rockville, Maryland 20857

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# ERYTHROMYCIN

## (e-rith-row-MY-sin)

Erythromycin is an antibiotic used to fight infection. Like all drugs, it has both benefits and risks. You should understand both benefits and risks before taking erythromycin. This leaflet contains important information about erythromycin and your health. Read it and save it for future reference. If you would like additional information about erythromycin, contact your doctor or your pharmacist. Your pharmacist can give you a more technical leaflet.

### Erythromycin is

- An antibiotic

### Forms available

- Tablets, capsules, liquids, injections

### Uses

- To fight infection
- For patients allergic to penicillin
- NOT effective against viruses or common cold

### Effects of the drug

- Small dose stops growth of bacteria so body can kill them

### How to take erythromycin

- Take on an empty stomach (at least one hour before meals or two hours after meals)
- If it causes an upset stomach, take it with milk
- Swallow tablets or capsules whole with water to avoid the bitter taste
- For the chewable tablet, chew it completely before swallowing

### Spacing of doses

- Take at prescribed intervals around the clock or take at evenly spaced intervals while awake

### If you miss a dose

- Take the missed dose immediately and take the rest of the day's doses at shorter, evenly spaced intervals
- Do not take two doses at the same time
- Take the right number of doses every day

### How long to take erythromycin

- Take as your doctor instructed
- Take all tablets or capsules in your prescription even if you are feeling better

### Talk to your doctor before taking erythromycin if

- You have ever had an allergic reaction, such as a rash or trouble breathing
- You have had liver trouble
- You are taking theophylline for asthma
  - Possible risks: can cause upset stomach, nausea, vomiting, restlessness, headache, nervousness, insomnia, irritability, confusion, or increased heart rate
- You are pregnant or nursing
  - Possible risks: erythromycin can pass to child

### Other precautions

- Throw away unused erythromycin
- Do not use for other infections
- Do not give erythromycin to anyone else
- Keep erythromycin out of reach of children

### Side effects

- Unwanted effects caused by a drug
- Erythromycin usually does not produce side effects

### Types of side effects:

- Gastrointestinal problems
  - Symptoms: nausea, vomiting, stomach cramps, or diarrhea
  - Action: prevent by taking drug with food
- Allergic reactions
  - Symptoms: mild skin rash with itching, hives with severe itching, trouble breathing
  - Action: if symptoms are severe, get emergency help immediately
- Fungus or yeast infection
  - Symptoms: mouth sores or vaginal itching or discharge
  - Action: call doctor
- Liver damage
  - Sometimes caused by estolate salt form of drug, e.g., Ilosone brand
- Symptoms: itching, dark urine, continuing fever, stomach pain, nausea, vomiting, yellow eyes and skin
- Action: stop taking erythromycin and call doctor

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reduced content/outline format

R-3-4

# ERYTHROMYCIN

## (e-rith-row-MY-sin)

This leaflet contains important information about erythromycin and your health. Read it and save it for future reference. If you would like additional information about erythromycin, contact your doctor or your pharmacist. Your pharmacist can give you a more technical leaflet.

### Erythromycin is

- An antibiotic

### Forms available

- Tablets, capsules, liquids, injections

### Uses

- To fight infection
- For patients allergic to penicillin
- NOT effective against viruses or common cold

### How to take erythromycin

- Take on an empty stomach (at least one hour before meals or two hours after meals)
- Swallow tablets or capsules whole with water

### Spacing of doses

- Take at prescribed intervals around the clock

### If you miss a dose

- Take the missed dose immediately
- Take the right number of doses every day

### How long to take erythromycin

- Take as your doctor instructed
- Take all tablets or capsules in your prescription even if you are feeling better

### Talk to your doctor before taking erythromycin if

- You have ever had an allergic reaction, such as a rash or trouble breathing
- You have had liver trouble
- You are taking theophylline for asthma
- You are pregnant or nursing
  - Possible risks: erythromycin can pass to child

### Other precautions

- Throw away unused erythromycin
- Do not use for other infections
- Do not give erythromycin to anyone else
- Keep erythromycin out of reach of children

### Side effects

- Unwanted effects caused by a drug
- Erythromycin usually does not produce side effects

### Types of side effects:

- Gastrointestinal problems
  - Symptoms: nausea, vomiting, stomach cramps, or diarrhea
  - Action: prevent by taking drug with food
- Allergic reactions
  - Symptoms: mild skin rash, trouble breathing
  - Action: if symptoms are severe, get emergency help immediately
- Fungus or yeast infection
  - Symptoms: mouth sores or vaginal itching or discharge
  - Action: call doctor
- Liver damage
  - Sometimes caused by estolate salt form of drug, e.g., Ilosone brand
  - Symptoms: itching, dark urine, continuing fever, stomach pain, nausea, vomiting, yellow eyes and skin
  - Action: stop taking erythromycin and call doctor

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5600 Fishers Lane  
Rockville, Maryland 20857

December 1979

# DALMANE

(DAL-main)

flurazepam  
(floor-AZZ-a-pam)

Dalmane is used to treat insomnia. Like all drugs, it has both benefits and risks. You should understand both benefits and risks before deciding to take Dalmane. This leaflet contains important information about Dalmane and your health. Read it and save it for future reference.

The first part of this leaflet summarizes the basic facts about Dalmane. Later parts give more detailed information about the drug, how it works, how to use it, what precautions you should take when using it, and what side effects you might have. If you would like additional information about Dalmane, contact your doctor or your pharmacist. Your pharmacist can give you a more technical leaflet to read.

## SUMMARY

Dalmane is a hypnotic drug (sleeping capsule). Most people fall asleep within half an hour after taking Dalmane and remain asleep for seven or eight hours.

Take only the dose of Dalmane your doctor recommends and take it only if you need it.

Alcohol (beer, wine, whiskey, etc.) and certain other drugs may increase the effects of Dal-

mane. Combining any of these with Dalmane may cause you to become over-sedated.

If you are allergic to Dalmane, or if you are a pregnant woman or a nursing mother, talk to your doctor before deciding to take Dalmane. Dalmane is not recommended for children, especially those under 15 years old. Do not take Dalmane if you need to be mentally alert. If you think that you or someone else may have taken an overdose, get emergency help immediately.

Dalmane can cause a number of side effects. Some people have "hangover" effects after they wake up. If you have any side effects that bother you, check with your doctor or pharmacist.

## WHAT DALMANE IS

Dalmane is the brand name of a hypnotic drug (sleeping capsule) called flurazepam. Dalmane is a member of a class of drugs called benzodiazepines. This class of drugs also includes Valium, Librium (chlordiazepoxide), Serax, Verstram, Tranxene and Ativan.

Dalmane comes in capsules in two different strengths. The 15 milligram capsule is orange and ivory. The stronger 30 milligram capsule is red and ivory.

## HOW DALMANE WORKS

Your doctor probably prescribed Dalmane to treat insomnia (trouble sleeping). Frequently nervous tension or stressful situations (such as family or job problems) cause temporary insomnia. In some cases, the insomnia may continue until the stressful situation ends. If you have this problem, your doctor may recommend that you use Dalmane several nights until you can fall asleep naturally. It

may help you fall asleep, remain asleep through the night, and sleep longer in the morning.

Sometimes doctors also prescribe Dalmane for patients who are recovering from certain medical problems and require extra sleep to aid their recovery.

Dalmane usually starts working within a half hour after a person takes it and continues working for seven or eight hours. You might also find that Dalmane has a stronger effect after you have taken it for a few nights. This is because Dalmane builds up in your body during the period that you take it.

## HOW TO USE DALMANE

Your doctor probably told you to take one Dalmane capsule at bedtime. Follow your doctor's instructions and take Dalmane only if you can't sleep. Once you have taken a capsule, do not take another one unless your doctor told you to.

You should not smoke heavily while taking Dalmane. Do not drink a lot of coffee, tea, or cola during the four hours before bedtime. These things may interfere with Dalmane's effectiveness. If you take an antacid while you are taking Dalmane, it may take a little longer for you to fall asleep. The antacid will coat your stomach and may prevent the Dalmane from entering your bloodstream.

Do not take Dalmane for a long period of time. Take it only when you have trouble falling asleep naturally. People who have trouble sleeping often get over the difficulty in a short period of time. If taking Dalmane does not help you sleep, do not increase the dosage. Tell your doctor.

Drugs similar to Dalmane can cause dependence. To avoid any possibility of dependence



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on Dalmane, take it only as directed and do not take it for a long time. If you have been taking Dalmane for a long time, do not stop taking it until you discuss this with your doctor. When people stop taking drugs similar to Dalmane, they sometimes have withdrawal symptoms, such as stomach or muscle cramps, sweating, shaking, vomiting, or convulsions. Dalmane might cause similar withdrawal symptoms.

## PRECAUTIONS

If you have had an allergic reaction to Dalmane or any related drugs (Valium, Librium, Serax, Verstram, Tranxene, and Ativan), do not take it.

Do not give Dalmane to children, especially those under the age of fifteen. Dalmane's effects on children have not been adequately studied.

Drugs similar to Dalmane cause birth defects. Dalmane might also cause birth defects. The risk is greatest if a pregnant woman takes the drug during the first three months of the pregnancy. Because insomnia is not usually a serious medical problem, you should not take Dalmane if you are pregnant.

If you are a nursing mother, Dalmane could enter your breast milk and make your child groggy or otherwise harm him or her.

Since Dalmane will make you sleepy, do not use it when you need to be mentally alert. Do not take Dalmane when driving, using machinery, etc. Also, do not smoke in bed after taking Dalmane. In general, you should be extra careful doing even everyday tasks while you are taking Dalmane.

While you are taking Dalmane, do not drink alcohol. Check with your doctor before taking Dalmane with antihistamines (for allergies),

cough and cold medicines, tranquilizers, anticonvulsants (for epilepsy), antidepressants (mood altering drugs), or narcotics (including pain killers). Because all of these drugs make people sleepy, taking two or more of them together increases their effects. It could produce increased drowsiness, confusion, or even coma.

Dalmane can also increase the effects of drugs used during surgery. If you plan to have surgery, including dental surgery, tell your doctor or dentist that you have been taking Dalmane.

It is possible to take an overdose of Dalmane. Sometimes, people take too many capsules when they are already sleepy from the drug.

The symptoms of an overdose include: drowsiness, sleepiness, confusion, and coma. These are similar to the normal effects of the drug, but they are much more severe. If you think that you or someone else may have taken an overdose **GET EMERGENCY HELP IMMEDIATELY.**

This drug is for you only. Do not give it to anyone else. Keep Dalmane and all medication where children cannot reach them.

## SIDE EFFECTS

Side effects are unwanted effects caused by a drug. Not everyone who takes Dalmane will experience side effects. In fact, many people have none. Older people and people in a weak physical condition are more likely to have side effects. If you have any troublesome side effects, contact your doctor.

**HANGOVER EFFECTS.** You may feel dizzy, drowsy, or sluggish after waking up. You may have trouble standing, walking, or keeping your balance. Sometimes these symptoms

continue throughout the day. Of course, you would expect a drug that helps you sleep to produce such symptoms. If you have any of these symptoms, sit or lie down immediately. Usually, hangover effects disappear within a few days. If the symptoms continue after the first few days, tell your doctor.

**PARADOXICAL EFFECTS.** Instead of falling asleep after taking Dalmane, some people become nervous, talkative, apprehensive, irritable or excited. They may even have hallucinations. If you have any of these reactions, stop taking the drug and tell your doctor.

**UNUSUAL SIDE EFFECTS.** A number of other side effects occur less often. These include: skin rash, headache, fever, sore throat, heartburn, nausea, vomiting, diarrhea, constipation, gastrointestinal pain, weakness, heart palpitation, yellowing of the skin or eyes, chest pains, body and joint pains, and genitourinary problems.

A number of other side effects are extremely rare. These include: sweating, flushes, blurred vision, difficulty in focusing the eyes, burning eyes, fainting, low blood pressure, shortness of breath, itching, dry mouth, bitter taste, excessive salivation, loss of appetite, euphoria, depression, slurred speech, confusion, restlessness, excitedness, or talkativeness, hallucinations, blood disorders, and elevated liver function blood tests. If you take Dalmane for a long time, it might cause some of these side effects. For this reason, your doctor may wish to perform some laboratory tests to check your liver, kidneys, and blood.

Prepared and distributed by Prescription Drug Labeling  
5800 Fishers Lane  
Rockville, Maryland 20857

September 1979

# DALMANE

(DAL-main)

flurazepam  
(floor-AZZ-a-pam)

Dalmane is used to treat insomnia. Like all drugs, it has both benefits and risks. You should understand both benefits and risks before deciding to take Dalmane. This leaflet contains important information about Dalmane and your health. Read it and save it for future reference.

The first part of this leaflet summarizes the basic facts about Dalmane. Later parts give more detailed information about the drug, how it works, how to use it, what precautions you should take when using it, and what side effects you might have. If you would like additional information about Dalmane, contact your doctor or your pharmacist. Your pharmacist can give you a more technical leaflet to read.

## SUMMARY

Dalmane is a hypnotic drug (sleeping capsule). Most people fall asleep within half an hour after taking Dalmane and remain asleep for seven or eight hours.

Take only the dose of Dalmane your doctor recommends and take it only if you need it.

Alcohol (beer, wine, whiskey, etc.) and certain other drugs may increase the effects of Dalmane. Combining any of these with Dalmane may cause you to become over-sedated.

If you are allergic to Dalmane, or if you are a pregnant woman or a nursing mother, talk to your doctor before deciding to take Dalmane. Dalmane is not recommended for children, especially those under 15 years old. Do not take Dalmane if you need to be mentally alert. If you think that you or someone else may have taken an overdose, get emergency help immediately.

Dalmane can cause a number of side effects. Some people have "hangover" effects after they wake up. If you have any side effects that bother you, check with your doctor or pharmacist.

## WHAT DALMANE IS

Dalmane is the brand name of a hypnotic drug (sleeping capsule) called flurazepam. Dalmane is a member of a class of drugs called benzodiazepines. This class of drugs also includes Valium, Librium (chlordiazepoxide), Serax, Verstram, Tranxene and Ativan.

Dalmane comes in capsules in two different strengths. The 15 milligram capsule is orange and ivory. The stronger 30 milligram capsule is red and ivory.

## HOW DALMANE WORKS

Your doctor probably prescribed Dalmane to treat insomnia (trouble sleeping).

Sometimes doctors also prescribe Dalmane for patients who are recovering from certain

medical problems and require extra sleep to aid their recovery.

Dalmane usually starts working within a half hour after a person takes it and continues working for seven or eight hours. You might also find that Dalmane has a stronger effect after you have taken it for a few nights.

## HOW TO USE DALMANE

Your doctor probably told you to take one Dalmane capsule at bedtime. Follow your doctor's instructions and take Dalmane only if you can't sleep. Be sure to give yourself enough time to fall asleep naturally before you decide to take Dalmane. Once you have taken a capsule, do not take another one unless your doctor told you to.

You should not smoke heavily while taking Dalmane. Do not drink a lot of coffee, tea, or cola during the four hours before bedtime. If you take an antacid while you are taking Dalmane, it may take a little longer for you to fall asleep.

Do not take Dalmane for a long period of time. Take it only when you have trouble falling asleep naturally. If you find it necessary to take it several nights in a row, try omitting the dose for a night or two. See if you can sleep without it. If taking Dalmane does not help you sleep, do not increase the dosage. Tell your doctor.

Drugs similar to Dalmane can cause dependence. To avoid any possibility of dependence on Dalmane, take it only as directed and do not take it for a long time. If you have been taking Dalmane for a long time, do not stop taking it until you discuss this with your doctor.

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## PRECAUTIONS

If you have had an allergic reaction to Dalmane or any related drugs (Valium, Librium, Serax, Verstram, Tranxene, and Ativan), do not take it.

Do not give Dalmane to children, especially those under the age of fifteen. Dalmane's effects on children have not been adequately studied.

Drugs similar to Dalmane cause birth defects. Dalmane might also cause birth defects.

If you are a nursing mother, Dalmane could enter your breast milk and pass to your child.

Since Dalmane will make you sleepy, do not use it when you need to be mentally alert. Do not take Dalmane when driving, using machinery, etc. Also, do not smoke in bed after taking Dalmane. In general, you should be extra careful doing even everyday tasks while you are taking Dalmane. For example, be careful when using household appliances, doing household repairs, climbing ladders, etc.

While you are taking Dalmane, do not drink alcohol. Check with your doctor before taking Dalmane with antihistamines (for allergies), cough and cold medicines, tranquilizers, anticonvulsants (for epilepsy), antidepressants (mood altering drugs), or narcotics (including pain killers).

Dalmane can also increase the effects of drugs used during surgery. If you plan to have surgery, including dental surgery, tell your doctor or dentist that you have been taking Dalmane.

It is possible to take an overdose of Dalmane. In order to avoid an overdose, keep your

prescription container away from the bed. Put only one dose of Dalmane at your bedside.

The symptoms of an overdose include: drowsiness, sleepiness, confusion, and coma. These are similar to the normal effects of the drug, but they are much more severe. If you think that you or someone else may have taken an overdose **GET EMERGENCY HELP IMMEDIATELY**. Call your doctor or the emergency room of the nearest hospital. Make sure they know that the person who has overdosed has been taking Dalmane. If possible, give them the prescription container.

This drug is for you only. Do not give it to anyone else. Keep Dalmane and all medication where children cannot reach them. For example, store them on a high shelf or in a locked cabinet.

## SIDE EFFECTS

Side effects are unwanted effects caused by a drug. Not everyone who takes Dalmane will experience side effects. In fact, many people have none. Older people and people in a weak physical condition are more likely to have side effects. If you have any troublesome side effects, contact your doctor.

**HANGOVER EFFECTS.** You may feel dizzy, drowsy, or sluggish after waking up. You may have trouble standing, walking, or keeping your balance. Sometimes these symptoms continue throughout the day. Of course, you would expect a drug that helps you sleep to produce such symptoms. If you have any of these symptoms, sit or lie down immediately. Usually, hangover effects disappear within a few days. If the symptoms continue after the first few days, tell your doctor.

**PARADOXICAL EFFECTS.** Instead of falling asleep after taking Dalmane, some people become nervous, talkative, apprehensive, irritable or excited. They may even have hallucinations. If you have any of these reactions, stop taking the drug and tell your doctor.

**UNUSUAL SIDE EFFECTS.** A number of other side effects occur less often. These include: skin rash, headache, fever, sore throat, heartburn, nausea, vomiting, diarrhea, constipation, gastrointestinal pain, weakness, heart palpitation, yellowing of the skin or eyes, chest pains, body and joint pains, and genitourinary problems.

A number of other side effects are extremely rare. These include: sweating, flushes, blurred vision, difficulty in focusing the eyes, burning eyes, fainting, low blood pressure, shortness of breath, itching, dry mouth, bitter taste, excessive salivation, loss of appetite, euphoria, depression, slurred speech, confusion, restlessness, excitedness, or talkativeness, hallucinations, blood disorders, and elevated liver function blood tests. If you take Dalmane for a long time, it might cause some of these side effects. For this reason, your doctor may wish to perform some laboratory tests to check your liver, kidneys, and blood.

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5800 Fishers Lane  
Rockville, Maryland 20857

September 1979

explanation/specific instructions

## DALMANE

(DAL-main)

**flurazepam**  
(floor-AZZ-a-pam)

Dalmane is used to treat insomnia. Like all drugs, it has both benefits and risks. You should understand both benefits and risks before deciding to take Dalmane. This leaflet contains important information about Dalmane and your health. Read it and save it for future reference.

The first part of this leaflet summarizes the basic facts about Dalmane. Later parts give more detailed information about the drug, how it works, how to use it, what precautions you should take when using it, and what side effects you might have. If you would like additional information about Dalmane, contact your doctor or your pharmacist. Your pharmacist can give you a more technical leaflet to read.

### SUMMARY

Dalmane is a hypnotic drug (sleeping capsule). Most people fall asleep within half an hour after taking Dalmane and remain asleep for seven or eight hours.

Take only the dose of Dalmane your doctor recommends and take it only if you need it.

Alcohol (beer, wine, whiskey, etc.) and certain other drugs may increase the effects of Dalmane. Combining any of these with Dalmane may cause you to become over-sedated.

If you are allergic to Dalmane, or if you are a pregnant woman or a nursing mother, talk to your doctor before deciding to take Dalmane. Dalmane is not recommended for children, especially those under 15 years old. Do not take Dalmane if you need to be mentally alert. If you think that you or someone else may have taken an overdose, get emergency help immediately.

Dalmane can cause a number of side effects. Some people have "hangover" effects after they wake up. If you have any side effects that bother you, check with your doctor or pharmacist.

### WHAT DALMANE IS

Dalmane is the brand name of a hypnotic drug (sleeping capsule) called flurazepam. Dalmane is a member of a class of drugs called benzodiazepines. This class of drugs also includes Valium, Librium (chloridiazepoxide), Serax, Verstram, Tranxene and Ativan.

Dalmane comes in capsules in two different strengths. The 15 milligram capsule is orange and ivory. The stronger 30 milligram capsule is red and ivory.

### HOW DALMANE WORKS

Your doctor probably prescribed Dalmane to treat insomnia (trouble sleeping). Frequently nervous tension or stressful situations (such as family or job problems) cause temporary insomnia. In some cases, the insomnia may continue until the stressful situation ends. If you have this problem, your doctor may recommend that you use Dalmane several nights until you can fall asleep naturally. It may help you fall asleep, remain asleep through the night, and sleep longer in the morning.

Sometimes doctors also prescribe Dalmane for patients who are recovering from certain

medical problems and require extra sleep to aid their recovery.

Dalmane usually starts working within a half hour after a person takes it and continues working for seven or eight hours. You might find that Dalmane has a stronger effect after you have taken it for a few nights. This is because Dalmane builds up in your body during the period that you take it.

### HOW TO USE DALMANE

Your doctor probably told you to take one Dalmane capsule at bedtime. Follow your doctor's instructions and take Dalmane only if you can't sleep. Be sure to give yourself enough time to fall asleep naturally before you decide to take Dalmane. Once you have taken a capsule, do not take another one unless your doctor told you to.

You should not smoke heavily while taking Dalmane. Do not drink a lot of coffee, tea, or cola during the four hours before bedtime. These things may interfere with Dalmane's effectiveness. If you take an antacid while you are taking Dalmane, it may take a little longer for you to fall asleep. The antacid will coat your stomach and may prevent the Dalmane from entering your bloodstream.

Do not take Dalmane for a long period of time. Take it only when you have trouble falling asleep naturally. People who have trouble sleeping often get over the difficulty in a short period of time. If you find it necessary to take it several nights in a row, try omitting the dose for a night or two. See if you can sleep without it. If taking Dalmane does not help you sleep, do not increase the dosage. Tell your doctor.

Drugs similar to Dalmane can cause dependence. To avoid any possibility of dependence on Dalmane, take it only as directed and do not take it for a long time. If you have been taking Dalmane for a long time, do not stop taking it

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until you discuss this with your doctor. When people stop taking drugs similar to Dalmane, they sometimes have withdrawal symptoms, such as stomach or muscle cramps, sweating, shaking, vomiting, or convulsions. Dalmane might cause similar withdrawal symptoms.

## PRECAUTIONS

If you have had an allergic reaction to Dalmane or any related drugs (Valium, Librium, Serax, Verstram, Tranxene, and Ativan), do not take it.

Do not give Dalmane to children, especially those under the age of fifteen. Dalmane's effects on children have not been adequately studied.

Drugs similar to Dalmane cause birth defects. Dalmane might also cause birth defects. The risk is greatest if a pregnant woman takes the drug during the first three months of the pregnancy. Because insomnia is not usually a serious medical problem, you should not take Dalmane if you are pregnant.

If you are a nursing mother, Dalmane could enter your breast milk and make your child groggy or otherwise harm him or her.

Since Dalmane will make you sleepy, do not use it when you need to be mentally alert. Do not take Dalmane when driving, using machinery, etc. Also, do not smoke in bed after taking Dalmane. In general, you should be extra careful doing even everyday tasks while you are taking Dalmane. For example, be careful when using household appliances, doing household repairs, climbing ladders, etc.

While you are taking Dalmane, do not drink alcohol. Check with your doctor before taking Dalmane with antihistamines (for allergies), cough and cold medicines, tranquilizers, anticonvulsants (for epilepsy), antidepressants (mood altering drugs), or narcotics (including

pain killers). Because all of these drugs make people sleepy, taking two or more of them together increases their effects. It could produce increased drowsiness, confusion, or even coma.

Dalmane can also increase the effects of drugs used during surgery. If you plan to have surgery, including dental surgery, tell your doctor or dentist that you have been taking Dalmane.

It is possible to take an overdose of Dalmane. Sometimes, people take too many capsules when they are already sleepy from the drug. In order to avoid an overdose, keep your prescription container away from the bed. Put only one dose of Dalmane at your bedside.

The symptoms of an overdose include: drowsiness, sleepiness, confusion, and coma. These are similar to the normal effects of the drug, but they are much more severe. If you think that you or someone else may have taken an overdose GET EMERGENCY HELP IMMEDIATELY. Call your doctor or the emergency room of the nearest hospital. Make sure they know that the person who has overdosed has been taking Dalmane. If possible, give them the prescription container.

This drug is for you only. Do not give it to anyone else. Keep Dalmane and all medication where children cannot reach them. For example, store them on a high shelf or in a locked cabinet.

## SIDE EFFECTS

Side effects are unwanted effects caused by a drug. Not everyone who takes Dalmane will experience side effects. In fact, many people have none. Older people and people in a weak physical condition are more likely to have side effects. If you have any troublesome side effects, contact your doctor.

**HANGOVER EFFECTS.** You may feel dizzy, drowsy, or sluggish after waking up. You may have trouble standing, walking, or keeping your balance. Sometimes these symptoms continue throughout the day. Of course, you would expect a drug that helps you sleep to produce such symptoms. If you have any of these symptoms, sit or lie down immediately. Usually, hangover effects disappear within a few days. If the symptoms continue after the first few days, tell your doctor.

**PARADOXICAL EFFECTS.** Instead of falling asleep after taking Dalmane, some people become nervous, talkative, apprehensive, irritable or excited. They may even have hallucinations. If you have any of these reactions, stop taking the drug and tell your doctor.

**UNUSUAL SIDE EFFECTS.** A number of other side effects occur less often. These include: skin rash, headache, fever, sore throat, heartburn, nausea, vomiting, diarrhea, constipation, gastrointestinal pain, weakness, heart palpitation, yellowing of the skin or eyes, chest pains, body and joint pains, and genitourinary problems.

A number of other side effects are extremely rare. These include: sweating, flushes, blurred vision, difficulty in focusing the eyes, burning eyes, fainting, low blood pressure, shortness of breath, itching, dry mouth, bitter taste, excessive salivation, loss of appetite, euphoria, depression, slurred speech, confusion, restlessness, excitedness, or talkativeness, hallucinations, blood disorders, and elevated liver function blood tests. If you take Dalmane for a long time, it might cause some of these side effects. For this reason, your doctor may wish to perform some laboratory tests to check your liver, kidneys, and blood.

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Core version  
no explanation  
no specific instructions  
simplified writing  
no risk emphasis  
text format  
full content

D-2-1

## DALMANE

(DAL-main)

**flurazepam**  
**(floor-AZZ-a-pam)**

Dalmane is used to treat insomnia. Like all drugs, it has both benefits and risks. You should understand both benefits and risks before deciding to take Dalmane. This leaflet contains important information about Dalmane and your health. Read it and save it for future reference.

The first part of this leaflet summarizes the basic facts about Dalmane. Later parts give more detailed information about the drug, how it works, how to use it, what precautions you should take when using it, and what side effects you might have. If you would like additional information about Dalmane, contact your doctor or your pharmacist. Your pharmacist can give you a more technical leaflet to read.

### SUMMARY

Dalmane is a hypnotic drug (sleeping capsule). Most people fall asleep within half an hour after taking Dalmane and remain asleep for seven or eight hours.

Take only the dose of Dalmane your doctor recommends and take it only if you need it.

Alcohol (beer, wine, whiskey, etc.) and certain other drugs may increase the effects of Dalmane. Combining any of these with Dalmane may cause you to become over-sedated.

If you are allergic to Dalmane, or if you are a pregnant woman or a nursing mother, talk to your doctor before deciding to take Dalmane. Dalmane is not recommended for children, especially those under 15 years old. Do not take Dalmane if you need to be mentally alert. If you think that you or someone else may have taken an overdose, get emergency help immediately.

Dalmane can cause a number of side effects. Some people have "hangover" effects after

they wake up. If you have any side effects that bother you, check with your doctor or pharmacist.

### WHAT DALMANE IS

Dalmane is the brand name of a hypnotic drug (sleeping capsule) called flurazepam. Dalmane is a member of a class of drugs called benzodiazepines. This class of drugs also includes Valium, Librium (chlordiazepoxide), Serax, Verstram, Tranxene and Ativan.

Dalmane comes in capsules in two different strengths. The 15 milligram capsule is orange and ivory. The stronger 30 milligram capsule is red and ivory.

### HOW DALMANE WORKS

Your doctor probably prescribed Dalmane to treat insomnia (trouble sleeping).

Sometimes doctors also prescribe Dalmane for patients who are recovering from certain medical problems and require extra sleep to aid their recovery.

Dalmane usually starts working within a half hour after a person takes it and continues working for seven or eight hours. You might find that Dalmane has a stronger effect after you have taken it for a few nights.

### HOW TO USE DALMANE

Your doctor probably told you to take one Dalmane capsule at bedtime. Follow your doctor's instructions and take Dalmane only if you can't sleep. Once you have taken a capsule, do not take another one unless your doctor told you to.

You should not smoke heavily while taking Dalmane. Do not drink a lot of coffee, tea, or cola during the four hours before bedtime. If you take an antacid while you are taking Dalmane, it may take a little longer for you to fall asleep.

Do not take Dalmane for a long period of time. Take it only when you have trouble falling asleep naturally. If taking Dalmane does not help you sleep, do not increase the dosage. Tell your doctor.

Drugs similar to Dalmane can cause dependence. To avoid any possibility of dependence

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on Dalmane, take it only as directed and do not take it for a long time. If you have been taking Dalmane for a long time, do not stop taking it until you discuss this with your doctor.

## PRECAUTIONS

If you have had an allergic reaction to Dalmane or any related drugs (Valium, Librium, Serax, Verstram, Tranxene, and Ativan), do not take it.

Do not give Dalmane to children, especially those under the age of fifteen. Dalmane's effects on children have not been adequately studied.

Drugs similar to Dalmane cause birth defects. Dalmane might also cause birth defects.

If you are a nursing mother, Dalmane could enter your breast milk and pass to your child.

Since Dalmane will make you sleepy, do not use it when you need to be mentally alert. Do not take Dalmane when driving, using machinery, etc. Also, do not smoke in bed after taking Dalmane. In general, you should be extra careful doing even everyday tasks while you are taking Dalmane.

While you are taking Dalmane, do not drink alcohol. Check with your doctor before taking Dalmane with antihistamines (for allergies), cough and cold medicines, tranquilizers, anticonvulsants (for epilepsy), antidepressants (mood altering drugs), or narcotics (including pain killers).

Dalmane can also increase the effects of drugs used during surgery. If you plan to have surgery, including dental surgery, tell your doctor or dentist that you have been taking Dalmane.

It is possible to take an overdose of Dalmane. The symptoms of an overdose include: drowsiness, sleepiness, confusion, and coma. These are similar to the normal effects of the drug, but they are much more severe. If you think that you or someone else may have taken an overdose GET EMERGENCY HELP IMMEDIATELY.

This drug is for you only. Do not give it to anyone else. Keep Dalmane and all medication where children cannot reach them.

## SIDE EFFECTS

Side effects are unwanted effects caused by a drug. Not everyone who takes Dalmane will experience side effects. In fact, many people have none. Older people and people in a weak physical condition are more likely to have side effects. If you have any troublesome side effects, contact your doctor.

**HANGOVER EFFECTS.** You may feel dizzy, drowsy, or sluggish after waking up. You may have trouble standing, walking, or keeping your balance. Sometimes these symptoms continue throughout the day. Of course, you would expect a drug that helps you sleep to produce such symptoms. If you have any of these symptoms, sit or lie down immediately. Usually, hangover effects disappear within a few days. If the symptoms continue after the first few days, tell your doctor.

**PARADOXICAL EFFECTS.** Instead of falling asleep after taking Dalmane, some people become nervous, talkative, apprehensive, irritable or excited. They may even have hallucinations. If you have any of these reactions, stop taking the drug and tell your doctor.

**UNUSUAL SIDE EFFECTS.** A number of other side effects occur less often. These include: skin rash, headache, fever, sore throat, heartburn, nausea, vomiting, diarrhea, constipation, gastrointestinal pain, weakness, heart palpitation, yellowing of the skin or eyes, chest pains, body and joint pains, and genitourinary problems.

A number of other side effects are extremely rare. These include: sweating, flushes, blurred vision, difficulty in focusing the eyes, burning eyes, fainting, low blood pressure, shortness of breath, itching, dry mouth, bitter taste, excessive salivation, loss of appetite, euphoria, depression, slurred speech, confusion, restlessness, excitedness, or talkativeness, hallucinations, blood disorders, and elevated liver function blood tests. If you take Dalmane for a long time, it might cause some of these side effects. For this reason, your doctor may wish to perform some laboratory tests to check your liver, kidneys, and blood.

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complex writing/no risk emphasis

D-2-2

# **DALMANE**

## **(DAL-main)**

### **flurazepam**

#### **(floor-AZZ-a-pam)**

Dalmane is used to treat insomnia. Like all drugs, Dalmane has both benefits and risks. These benefits and risks should be considered before deciding to take the drug. Some important information about Dalmane is provided by this leaflet. It should be read and put aside for future reference.

First the basic facts about Dalmane are summarized. Then more detailed information is given about the drug, how it works, how it should be used, what precautions to take when using it, and what side effects might occur. If additional information about Dalmane is desired, contact your physician or your pharmacist. A more technical leaflet can be obtained from your pharmacist.

#### **SUMMARY**

Dalmane is a hypnotic drug (sleeping capsule). The hypnotic effect of Dalmane is usually felt within a half hour after taking it and continues for seven or eight hours.

Only the recommended dose of Dalmane should be taken and only when necessary.

Alcohol (beer, wine, whiskey, etc.) and certain other drugs may increase the effects of Dalmane. Combining any of these with Dalmane may cause you to become oversedated.

Those who are pregnant, nursing a child, or allergic to Dalmane should talk to their physician before deciding to take Dalmane. Dalmane is not recommended for children, especially those under 15 years old. Do not take Dalmane if you need to be mentally alert. In the event of an overdose, get emergency help immediately.

Dalmane can cause a number of side effects, including "hangover" effects which are sometimes experienced after waking up. Bother-some side effects should be reported to your physician or pharmacist.

#### **WHAT DALMANE IS**

Dalmane is the brand name of a hypnotic drug called flurazepam and is related chemically to other benzodiazepines (Valium, Librium, Serax, Verstran, Tranxene and Ativan).

Two different strengths of Dalmane are available. A 15 milligram capsule is orange and ivory; the stronger 30 milligram capsule is red and ivory.

#### **HOW DALMANE WORKS**

Dalmane is usually prescribed to treat insomnia (difficulty in falling asleep).

Dalmane is also prescribed to treat certain medical conditions requiring restful sleeping periods for recuperation.

The sleep-inducing effects of Dalmane will usually be felt within a half hour of taking the drug and last for about seven or eight hours.

Often the drug will have a stronger effect when used over a number of consecutive nights.

#### **HOW TO USE DALMANE**

Physicians usually direct patients to take one Dalmane capsule at bedtime. Dalmane should be taken only as directed by your physician and should be taken only when you are unable to sleep. Once having taken a capsule, do not take another unless directed by your physician.

Patients should not smoke heavily while taking Dalmane. They should not drink a lot of coffee, tea, or cola during the four hours preceding bedtime. Use of antacids can also retard the effects of Dalmane.

Dalmane should not be taken on a long-term basis. It should be taken only when there is difficulty in falling asleep naturally. If taking Dalmane does not help you sleep, contact your physician, but avoid increasing the dosage on your own.

Drugs similar to Dalmane can cause dependence. The possibility of dependence is minimized when you take only the quantity your physician recommends, only as often as your physician recommends, and do not take it for a long time. If you have been taking Dalmane for a long time, it should not be discontinued before you have consulted your physician.



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## PRECAUTIONS

Patients who have had an allergic reaction to Dalmane or related drugs (Valium, Librium, Serax, Verstran, Tranxene, and Ativan) should not take Dalmane.

Children under 15 should not be given Dalmane. The effects of Dalmane in this age group have not been adequately studied.

Drugs similar to Dalmane have been associated with an increased incidence of birth defects. Dalmane might also cause birth defects.

If you are nursing, Dalmane could enter your milk supply and pass to your child.

Since Dalmane produces sleepiness, do not do anything requiring mental alertness after you take a Dalmane capsule. This includes driving, using machinery, etc. Do not smoke in bed after using Dalmane. In general, while taking Dalmane, you should be extra careful doing even everyday tasks.

While taking Dalmane, do not drink alcohol. Your physician should be consulted before you take Dalmane with antihistamines (for allergies), cough and cold medicines, tranquilizers, anticonvulsants (for epilepsy), antidepressants (mood altering drugs), or narcotics (including pain killers).

Dalmane can also increase the effects of drugs used during surgery. Consequently, your physician or, in the case of dental surgery, your dentist, should be aware that you have been taking Dalmane.

It is possible to take an overdose of Dalmane. Overdose symptoms include drowsiness, sleepiness, confusion, and coma. It may be difficult to distinguish the symptoms of an overdose from the natural action of the drug, but symptoms of overdose are much more severe. If an overdose is suspected, GET EMERGENCY HELP IMMEDIATELY.

This drug is to be administered only to the person for whom it has been prescribed. It should not be given to anyone else. Dalmane and all medications should be kept where children cannot reach them.

## SIDE EFFECTS

Side effects are unwanted effects caused by a drug. Not all persons experience side effects

when taking Dalmane, and many experience none. Side effects are seen more often in elderly or debilitated patients. However, if any troublesome side effects occur, notify your physician.

**HANGOVER EFFECTS.** Dalmane can cause dizziness, drowsiness, sluggishness, or balance problems after you arise. Sometimes these symptoms continue throughout the day. These symptoms are an extension of the natural action of the drug. If they occur, sit or lie down at the first sign of dizziness. Usually, hangover effects disappear within the first few days. If symptoms persist after that time, notify your physician.

**PARADOXICAL EFFECTS.** Instead of falling asleep after taking Dalmane, some people become nervous, talkative, apprehensive, irritable or excited, or even experience hallucinations. If these reactions occur, discontinue use of the drug and contact your physician.

**UNUSUAL SIDE EFFECTS.** Less common side effects that have been reported include: skin rash, headache, fever, sore throat, heartburn, nausea, vomiting, diarrhea, constipation, gastrointestinal pain, weakness, heart palpitation, jaundice, chest pains, body and joint pains, and genitourinary problems.

Side effects which are extremely rare but have been reported include: sweating, flushes, blurred vision, difficulty in focusing the eyes, burning eyes, fainting, hypotension, shortness of breath, itching, dry mouth, bitter taste, excessive salivation, loss of appetite, euphoria, depression, slurred speech, confusion, restlessness, excitedness, or talkativeness, hallucinations, blood disorders, and elevated liver function blood tests. Taken for a prolonged period, Dalmane might cause some of these side effects. Consequently, your physician may perform some laboratory tests to check your liver, kidneys, and blood.

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D-2-3

# DALMANE

## (DAL-main)

### flurazepam

### (floor-AZZ-a-pam)

Dalmane is used to treat insomnia. Like all drugs, it has risks. You should understand these risks before deciding to take Dalmane. This leaflet contains important information about Dalmane and your health. Read it and save it for future reference.

The first part of this leaflet summarizes the basic facts about Dalmane. Later parts give more detailed information about what precautions you should take when using it, what side effects you might have, what Dalmane is, how it works, and how it should be used. If you would like additional information about Dalmane, contact your doctor or your pharmacist. Your pharmacist can give you a more technical leaflet to read.

#### SUMMARY

*If you are allergic to Dalmane, or if you are a pregnant woman or a nursing mother, talk to your doctor before deciding to take Dalmane. Dalmane is not recommended for children, especially those under 15 years old. Do not take Dalmane if you need to be mentally alert. If you think that you or someone else may have taken an overdose, get emergency help immediately.*

*Alcohol (beer, wine, whiskey, etc.) and certain other drugs may increase the effects of Dalmane. Combining any of these with Dalmane may cause you to become oversedated.*

*Dalmane can cause a number of side effects. Some people have "hangover" effects after they wake up. If you have any side effects that bother you, check with your doctor or pharmacist.*

Dalmane is a hypnotic drug (sleeping capsule). Most people fall asleep within half an hour after taking Dalmane and remain asleep for seven or eight hours.

Take only the dose of Dalmane your doctor recommends and take it only if you need it.

#### PRECAUTIONS

*If you have had an allergic reaction to Dalmane or any related drugs (Valium, Librium, Serax, Verstram, Tranxene, and Ativan), do not take it.*

*Do not give Dalmane to children, especially those under the age of fifteen. Dalmane's effects on children have not been adequately studied.*

Drugs similar to Dalmane cause birth defects. *Dalmane might also cause birth defects.*

If you are a nursing mother, *Dalmane could enter your breast milk and pass to your child.*

*Since Dalmane will make you sleepy, do not use it when you need to be mentally alert. Do not take Dalmane when driving, using machinery, etc. Also, do not smoke in bed after taking Dalmane. In general, you should be extra careful doing even everyday tasks while you are taking Dalmane.*

*While you are taking Dalmane, do not drink alcohol. Check with your doctor before taking Dalmane with antihistamines (for allergies), cough and cold medicines, tranquilizers, anti-convulsants (for epilepsy), antidepressants (mood altering drugs), or narcotics (including pain killers).*

Dalmane can also increase the effects of drugs used during surgery. If you plan to have surgery, including dental surgery, tell your doctor or dentist that you have been taking Dalmane.

*It is possible to take an overdose of Dalmane. The symptoms of an overdose include: drowsiness, sleepiness, confusion, and coma. These are similar to the normal effects of the drug, but they are much more severe. If you think that you or someone else may have taken an overdose GET EMERGENCY HELP IMMEDIATELY.*

This drug is for you only. *Do not give it to anyone else. Keep Dalmane and all medication where children cannot reach them.*

#### SIDE EFFECTS

Side effects are unwanted effects caused by a drug. Not everyone who takes Dalmane will

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experience side effects. In fact, many people have none. Older people and people in a weak physical condition are more likely to have side effects. If you have any troublesome side effects, contact your doctor.

**HANGOVER EFFECTS.** *You may feel dizzy, drowsy, or sluggish after waking up. You may have trouble standing, walking, or keeping your balance. Sometimes these symptoms continue throughout the day.* Of course, you would expect a drug that helps you sleep to produce such symptoms. If you have any of these symptoms, sit or lie down immediately. Usually, hangover effects disappear within a few days. If the symptoms continue after the first few days, tell your doctor.

**PARADOXICAL EFFECTS.** Instead of falling asleep after taking Dalmane, some people become nervous, talkative, apprehensive, irritable or excited. They may even have hallucinations. If you have any of these reactions, stop taking the drug and tell your doctor.

**UNUSUAL SIDE EFFECTS.** A number of other side effects occur less often. These include: skin rash, headache, fever, sore throat, heartburn, nausea, vomiting, diarrhea, constipation, gastrointestinal pain, weakness, heart palpitation, yellowing of the skin or eyes, chest pains, body and joint pains, and genitourinary problems.

A number of other side effects are extremely rare. These include: sweating, flushes, blurred vision, difficulty in focusing the eyes, burning eyes, fainting, low blood pressure, shortness of breath, itching, dry mouth, bitter taste, excessive salivation, loss of appetite, euphoria, depression, slurred speech, confusion, restlessness, excitedness, or talkativeness, hallucinations, blood disorders, and elevated liver function blood tests. If you take Dalmane for a long time, it might cause some of these side effects. For this reason, your doctor may wish to perform some laboratory tests to check your liver, kidneys, and blood.

### WHAT DALMANE IS

Dalmane is the brand name of a hypnotic drug (sleeping capsule) called flurazepam. Dalmane is a member of a class of drugs called benzodiazepines. This class of drugs also includes Valium, Librium (chlordiazepoxide), Serax, Verstram, Tranxene and Ativan.

Dalmane comes in capsules in two different strengths. The 15 milligram capsule is orange

and ivory. The stronger 30 milligram capsule is red and ivory.

### HOW DALMANE WORKS

Your doctor probably prescribed Dalmane to treat insomnia (trouble sleeping).

Sometimes doctors also prescribe Dalmane for patients who are recovering from certain medical problems and require extra sleep to aid their recovery.

Dalmane usually starts working within a half hour after a person takes it and continues working for seven or eight hours. You might find that Dalmane has a stronger effect after you have taken it for a few nights.

### HOW TO USE DALMANE

Your doctor probably told you to take one Dalmane capsule at bedtime. Follow your doctor's instructions and take Dalmane only if you can't sleep. Once you have taken a capsule, do not take another one unless your doctor told you to.

You should not smoke heavily while taking Dalmane. Do not drink a lot of coffee, tea, or cola during the four hours before bedtime. If you take an antacid while you are taking Dalmane, it may take a little longer for you to fall asleep.

*Do not take Dalmane for a long period of time.* Take it only when you have trouble falling asleep naturally. People who have trouble sleeping often get over the difficulty in a short period of time. *If taking Dalmane does not help you sleep, do not increase the dosage.* Tell your doctor.

*Drugs similar to Dalmane can cause dependence.* To avoid any possibility of dependence on Dalmane, take it only as directed and do not take it for a long time. If you have been taking Dalmane for a long time, do not stop taking it until you discuss this with your doctor.

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## SIDE EFFECTS

Side effects are unwanted effects caused by a drug. Not all persons experience side effects when taking Dalmane, and many experience none. Side effects are seen more often in elderly or debilitated patients. However, if any troublesome side effects occur, notify your physician.

**HANGOVER EFFECTS.** *Dalmane can cause dizziness, drowsiness, sluggishness, or balance problems after you arise. Sometimes these symptoms continue throughout the day.* These symptoms are an extension of the natural action of the drug. If they occur, sit or lie down at the first sign of dizziness. Usually, hangover effects disappear within a few days. If symptoms persist after that time, notify your physician.

**PARADOXICAL EFFECTS.** Instead of falling asleep after taking Dalmane, some people become nervous, talkative, apprehensive, irritable or excited, or even experience hallucinations. If these reactions occur, discontinue use of the drug and contact your physician.

**UNUSUAL SIDE EFFECTS.** Less common side effects that have been reported include: skin rash, headache, fever, sore throat, heartburn, nausea, vomiting, diarrhea, constipation, gastrointestinal pain, weakness, heart palpitation, jaundice, chest pains, body and joint pains, and genitourinary problems.

Side effects which are extremely rare but have been reported include: sweating, flushes, blurred vision, difficulty in focusing the eyes, burning eyes, fainting, hypotension, shortness of breath, itching, dry mouth, bitter taste, excessive salivation, loss of appetite, euphoria, depression, slurred speech, confusion, restlessness, excitedness, or talkativeness, hallucinations, blood disorders, and elevated liver function blood tests. Taken for a prolonged period, Dalmane might cause some of these side effects. Consequently, your physician may perform some laboratory tests to check your liver, kidneys, and blood.

## WHAT DALMANE IS

Dalmane is the brand name of a hypnotic drug called flurazepam and is related chemically to other benzodiazepines (Valium, Librium, Serax, Verstran, Tranxene and Ativan).

Two different strengths of Dalmane are available. A 15 milligram capsule is orange and

ivory; the stronger 30 milligram capsule is red and ivory.

## HOW DALMANE WORKS

Dalmane is usually prescribed to treat insomnia (difficulty in falling asleep).

Dalmane is also prescribed to treat certain medical conditions requiring restful sleeping periods for recuperation.

The sleep-inducing effects of Dalmane will usually be felt within a half hour of taking the drug and last for about seven or eight hours. Often the drug will have a stronger effect when used over a number of consecutive nights.

## HOW TO USE DALMANE

Physicians usually direct patients to take one Dalmane capsule at bedtime. Dalmane should be taken only as directed by your physician and should be taken only when you are unable to sleep. Once having taken a capsule, do not take another unless directed by your physician.

Patients should not smoke heavily while taking Dalmane. They should not drink a lot of coffee, tea, or cola during the four hours preceding bedtime. Use of antacids can also retard the effects of Dalmane.

*Dalmane should not be taken on a long-term basis.* It should be taken only when there is difficulty in falling asleep naturally. *If taking Dalmane does not help you sleep, contact your physician, but avoid increasing the dosage on your own.*

*Drugs similar to Dalmane can cause dependence.* The possibility of dependence is minimized when you take only the quantity your physician recommends, only as often as your physician recommends, and do not take it for a long time. If you have been taking Dalmane for a long time, it should not be discontinued before you have consulted your physician.

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D-2-4

complex writing/risk emphasis

# DALMANE

## (DAL-main)

### flurazepam (floor-AZZ-a-pam)

Dalmane is used to treat insomnia. Like all drugs, Dalmane has risks. These risks should be considered before deciding to take the drug. Some important information about Dalmane is provided by this leaflet. It should be read and put aside for future reference.

First the basic facts about Dalmane are summarized. Then more detailed information is given about what precautions to take when using it, what side effects might occur, what Dalmane is, how it works and how it should be used. If additional information about Dalmane is desired, contact your physician or your pharmacist. A more technical leaflet can be obtained from your pharmacist.

#### SUMMARY

*Those who are pregnant, nursing a child, or allergic to Dalmane should talk to their physician before deciding to take Dalmane. Dalmane is not recommended for children, especially those under 15 years old. Do not take Dalmane if you need to be mentally alert. In the event of an overdose, get emergency help immediately.*

*Alcohol (beer, wine, whiskey, etc.) and certain other drugs may increase the effects of Dalmane. Combining any of these with Dalmane may cause you to become over-sedated.*

*Dalmane can cause a number of side effects, including "hangover" effects which are sometimes experienced after waking up. Bothering side effects should be reported to your physician or pharmacist.*

Dalmane is a hypnotic drug (sleeping capsule). The hypnotic effect of Dalmane is usually felt

within a half hour after taking it and continues for seven or eight hours.

Only the recommended dose of Dalmane should be taken and only when necessary.

#### PRECAUTIONS

*Patients who have had an allergic reaction to Dalmane or related drugs (Valium, Librium, Serax, Vertran, Tranxene, and Ativan) should not take Dalmane.*

*Children under 15 should not be given Dalmane. The effects of Dalmane in this age group have not been adequately studied.*

Drugs similar to Dalmane have been associated with an increased incidence of birth defects. *Dalmane might also cause birth defects.*

*If you are nursing, Dalmane could enter your milk supply and pass to your child.*

*Since Dalmane produces sleepiness, do not do anything requiring mental alertness after you take a Dalmane capsule. This includes driving, using machinery, etc. Do not smoke in bed after using Dalmane. In general, while taking Dalmane, you should be extra careful doing even everyday tasks.*

*While taking Dalmane, do not drink alcohol. Your physician should be consulted before you take Dalmane with antihistamines (for allergies), cough and cold medicines, tranquilizers, anticonvulsants (for epilepsy), antidepressants (mood altering drugs), or narcotics (including pain killers).*

Dalmane can also increase the effects of drugs used during surgery. Consequently, your physician or, in the case of dental surgery, your dentist, should be aware that you have been taking Dalmane.

*It is possible to take an overdose of Dalmane. Overdose symptoms include drowsiness, sleepiness, confusion, and coma. It may be difficult to distinguish the symptoms of an overdose from the natural action of the drug, but symptoms of overdose are much more severe. If an overdose is suspected, GET EMERGENCY HELP IMMEDIATELY.*

This drug is to be administered only to the person for whom it has been prescribed. *It should not be given to anyone else. Dalmane and all medications should be kept where children cannot reach them.*

reduced content/text format

D-3-2

# **DALMANE**

## **(DAL-main)**

### **flurazepam**

### **(floor-AZZ-a-pam)**

This leaflet contains important information about Dalmane and your health. Read it and save it for future reference. If you would like additional information about Dalmane, contact your doctor or your pharmacist. Your pharmacist can give you a more technical leaflet.

#### **WHAT DALMANE IS**

Dalmane comes in capsules in two different strengths. The 15 milligram capsule is orange and ivory. The stronger 30 milligram capsule is red and ivory.

#### **HOW DALMANE WORKS**

Your doctor probably prescribed Dalmane to treat insomnia (trouble sleeping).

Sometimes doctors also prescribe Dalmane for patients who are recovering from certain

medical problems and require extra sleep to aid their recovery.

Dalmane usually starts working within a half hour after a person takes it and continues working for seven or eight hours. You might find that Dalmane has a stronger effect after you have taken it for a few nights.

#### **HOW TO USE DALMANE**

Your doctor probably told you to take one Dalmane capsule at bedtime. Follow your doctor's instructions and take Dalmane only if you can't sleep. Once you have taken a capsule, do not take another one unless your doctor told you to.

You should not smoke heavily while taking Dalmane. Do not drink a lot of coffee, tea, or cola during the four hours before bedtime, or take an antacid.

Do not take Dalmane for a long period of time. Take it only when you have trouble falling asleep naturally. If taking Dalmane does not help you sleep, do not increase the dosage. Tell your doctor.

Drugs similar to Dalmane can cause dependence. To avoid any possibility of dependence on Dalmane, take it only as directed and do not take it for a long time. If you have been taking Dalmane for a long time, do not stop taking it until you discuss this with your doctor.

D-3-2

## PRECAUTIONS

If you have had an allergic reaction to Dalmane or any related drugs (Valium, Librium, Serax, Verstran, Tranxene, and Ativan), do not take it.

Do not give Dalmane to children, especially those under the age of fifteen.

Drugs similar to Dalmane cause birth defects. Dalmane might also cause birth defects.

If you are a nursing mother, Dalmane could enter your breast milk and pass to your child.

Since Dalmane will make you sleepy, do not use it when you need to be mentally alert.

While you are taking Dalmane, do not drink alcohol. Check with your doctor before taking Dalmane with antihistamines (for allergies), cough and cold medicines, tranquilizers, anti-convulsants (for epilepsy), antidepressants (mood altering drugs), or narcotics (including pain killers).

If you plan to have surgery, including dental surgery, tell your doctor or dentist that you have been taking Dalmane.

It is possible to take an overdose of Dalmane. The symptoms of an overdose include: drowsiness, sleepiness, confusion, and coma. If you think that you or someone else may have taken an overdose **GET EMERGENCY HELP IMMEDIATELY.**

This drug is for you only. Do not give it to anyone else. Keep Dalmane and all medication where children cannot reach them.

## SIDE EFFECTS

Most people who take Dalmane will experience no side effects. Older people and people in a weak physical condition are more likely to have side effects.

**HANGOVER EFFECTS.** You may feel dizzy, drowsy, or sluggish after waking up. You may have trouble standing, walking, or keeping your balance. If you have any of these symptoms, sit or lie down immediately.

Other side effects occur very infrequently. However, if you do experience any reactions, call your doctor.

Prepared and distributed by Prescription Drug Labeling  
5600 Fishers Lane  
Rockville, Maryland 20857

December 1979

full content/outline format

D-3-3

# **DALMANE**

## **(DAL-main)**

### **flurazepam**

### **(floor-AZZ-a-pam)**

Dalmane is used to treat insomnia. Like all drugs, it has both benefits and risks. You should understand both benefits and risks before deciding to take Dalmane. This leaflet contains important information about Dalmane and your health. Read it and save it for future reference. If you would like additional information about Dalmane, contact your doctor or your pharmacist. Your pharmacist can give you a more technical leaflet.

#### **Dalmane is**

- A hypnotic drug (sleeping pill)
- The brand name of flurazepam
- A member of a class of drugs including Valium, Librium (Chlordiazepoxide), Serax, Verstram, Tranxene, Ativan

#### **Forms available**

- 15 milligram capsule (orange and ivory)
- 30 milligram capsule (red and ivory)

#### **Uses**

- To treat insomnia
- For patients who require extra sleep to aid recovery from certain medical problems

#### **Effects of the drug**

- Helps you sleep
- Starts working within a half hour
- Continues working for seven or eight hours
- Can have a stronger effect if taken for several nights

#### **Spacing of doses**

- Follow doctor's instructions
- Take one capsule at bedtime
- Take only if you can't sleep
- Do not take more than one capsule unless doctor told you to

#### **While taking Dalmane, do not**

- Smoke heavily
- Drink a lot of coffee, tea, or cola during the four hours before bedtime
- Take antacid (may take longer to fall asleep)

#### **To avoid dependence and withdrawal symptoms**

- Take only as directed
- Do not take for long period of time
- Do not stop without consulting your doctor

#### **Do not take Dalmane if**

- You are allergic to Dalmane or related drugs (Valium, Librium, Serax, Verstram, Tranxene, or Ativan)

#### **Talk to your doctor before taking Dalmane if**

- You are pregnant
  - Possible risks: birth defects
- You are a nursing mother
  - Possible risks: Dalmane could enter your milk and pass to your child



D-3-3

#### To avoid accidents while using Dalmane

- Do not use it when you need to be mentally alert (e.g., when driving, using machinery, etc.)
- Do not smoke in bed
- Be extra careful doing even everyday tasks

#### To avoid interactions with other drugs

- Do not take with alcohol
- Do not take with antihistamines (for allergies), cough medicines, tranquilizers, anticonvulsants (for epilepsy), antidepressants (mood altering drugs), narcotics (including pain killers)
- Tell your doctor or dentist you have been taking Dalmane before any surgery

#### In case of overdose

- Symptoms: drowsiness, sleepiness, confusion, coma, similar to normal effects, but more severe
- Action: GET EMERGENCY HELP IMMEDIATELY

#### Other precautions

- Do not give Dalmane to children (effects not adequately studied)
- Do not give Dalmane to anyone else
- Keep Dalmane out of reach of children

#### Side effects

- Unwanted effects caused by a drug
- Many people have none
- People likely to have side effects: older people, people in weak physical condition

#### Types of side effects

##### ● Hangover effects

- Symptoms: feel dizzy, drowsy, or sluggish after waking up, have trouble standing, walking, or keeping your balance
- Duration: may continue throughout the day; usually disappear within a few days
- Action: sit or lie down immediately; if symptoms continue, tell doctor

##### ● Unusual side effects

- Occur less often: skin rash, headache, fever, sore throat, heartburn, nausea, vomiting, diarrhea, constipation, gastrointestinal pain, weakness, heart palpitation, yellowing of the skin or eyes, chest pains, body and joint pains, and genitourinary problems
- Occur rarely: sweating, flushes, blurred vision, difficulty in focusing the eyes, burning eyes, fainting, low blood pressure, shortness of breath, itching, dry mouth, bitter taste, excessive salivation, loss of appetite, euphoria, depression, slurred speech, confusion, restlessness, excitedness, or talkativeness, hallucinations, blood disorders, and elevated liver function blood tests

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5600 Fishers Lane  
Rockville, Maryland 20857

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reduced content/outline format

D-3-4

**DALMANE**  
(DAL-main)  
  
**flurazepam**  
(floor-AZZ-a-pam)

This leaflet contains important information about Dalmane and your health. Read it and save it for future reference. If you would like additional information about Dalmane, contact your doctor or your pharmacist. Your pharmacist can give you a more technical leaflet.

**Forms available**

- 15 milligram capsule (orange and ivory)
- 30 milligram capsule (red and ivory)

**Uses**

- To treat insomnia
- For patients who require extra sleep to aid recovery from certain medical problems

**Effects of the drug**

- Helps you sleep
- Starts working within a half hour
- Continues working for seven or eight hours
- Can have a stronger effect if taken for several nights

**Spacing of doses**

- Follow doctor's instructions
- Take one capsule at bedtime
- Take only if you can't sleep
- Do not take more than one capsule unless doctor told you to

**While taking Dalmane, do not**

- Smoke heavily
- Drink a lot of coffee, tea, or cola during the four hours before bedtime
- Take antacid

**To avoid dependence and withdrawal symptoms**

- Take only as directed
- Do not take for a long period of time
- Do not stop without consulting with your doctor

**Do not take Dalmane if**

- You are allergic to it or related drugs (Valium, Librium, Serax, Verstram, Tranxene, or Ativan)

**Talk to your doctor before taking Dalmane if**

- You are pregnant
  - Possible risks: birth defects
- You are a nursing mother
  - Possible risks: Dalmane could enter your breast milk and pass to your child

**To avoid accidents while using Dalmane**

- Do not use it when you need to be mentally alert

**To avoid interactions with other drugs**

- Do not take with alcohol
- Do not take with antihistamines (for allergies), cough medicines, tranquilizers, anticonvulsants (for epilepsy), antidepressants (mood altering drugs), narcotics (including pain killers)

**In case of overdose**

- Symptoms: drowsiness, sleepiness, coma
- Action: **GET EMERGENCY HELP IMMEDIATELY**

**Other precautions**

- Do not give Dalmane to children (effects not adequately studied)
- Do not give Dalmane to anyone else
- Keep Dalmane out of reach of children

**Side effects**

- Many people have none
- People likely to have side effects: older people, people in weak physical condition

**Type of side effects**

- Hangover effects
  - Symptoms: feel dizzy, drowsy, or sluggish after waking up, have trouble standing, walking, or keeping your balance
  - Action: sit or lie down immediately
- Other side effects: infrequent
  - If you experience reactions, call your doctor

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Appendix B

ERYTHROMYCIN TELEPHONE SURVEY

OMB# 57-S78005

EXPIRES 12/81

VERSION - 10/15/79

1-10/

CASE #

--	--	--	--	--	--	--	--

13-16/

PRESCRIPTION DRUG  
INFORMATION STUDY

TELEPHONE/PERSONAL INTERVIEW:  
ERYTHROMYCIN

CARD 01

11-12/



TIME BEGAN:

		:		
--	--	---	--	--

17-20/

AM..... 1

21/

PM..... 2

Hello, I'm \_\_\_\_\_, calling from The Rand Corporation in Santa Monica. We're doing a study for the U.S. Department of Health, Education, and Welfare about prescription drugs. When you picked up a prescription from (NAME OF PHARMACY) you signed an authorization form that let the pharmacy give us your name to be part of this study. I'd like to do an interview with you now, over the phone, if you have time.

1. Our record from the pharmacy shows you received a prescription drug on (DATE). Do you remember the name of the drug?  
IF "MORE THAN ONE:" Tell me all the prescriptions you received that day.  
IF "ANTIBIOTIC": Do you know the name of the particular antibiotic?

NAMES ERYTHROMYCIN OR TRADE

NAME...(GO TO Q.6)..... 1

22/

SAYS "ANTIBIOTIC" ONLY...

(ASK Q.2)..... 2

NAMES ONLY OTHER DRUGS...

(ASK Q.2)..... 3

DOESN'T KNOW NAME...(ASK Q.2). 4

2. Did you receive a prescription for erythromycin? IF "NO" OR UNSURE  
PROBE: This drug is also called (TRADE NAME).

SAID "ANTIBIOTIC" IN Q.1,  
CONFIRMS IT'S ERYTHROMYCIN...

(GO TO Q.7)..... 1

23/

NOW REMEMBERS ERYTHROMYCIN

(GO TO Q.6)..... 2

DIDN'T RECEIVE OR NOT SURE...

(ASK Q.3)..... 3

3. This drug was in the form of pills. It cost (AMOUNT).

RECEIVED ERYTHROMYCIN...  
(GO TO Q.6)..... 1 24/

DIDN'T RECEIVE OR UNSURE...  
(ASK TO Q.4)..... 2

4. This drug is an antibiotic, prescribed for infections.

RECEIVED ERYTHROMYCIN...  
(GO TO Q.7)..... 1 25/

DIDN'T RECEIVE, OR UNSURE...  
(READ Q.5)..... 2

5. Since we're not sure you received erythromycin I'd like to check our records again before we do the interview. This is not something you should worry about. Occasionally we have small mix-ups. I'll check it carefully and call you back to tell you what I find out.

TERMINATE INTERVIEW AND SEE YOUR SUPERVISOR.

6. What kind of a drug is erythromycin? Would you say it's:

a tranquilizer,..... 1 26/

an antibiotic,..... 2

a sleeping pill,..... 3

or something else?..... 4

(SPECIFY) \_\_\_\_\_

DON'T KNOW..... 5

7. Was this prescription a new prescription or was it a refill?  
(PROBE: Did your doctor give you a prescription or call an order into the pharmacy for the pills you received on (DATE) or did the pharmacy already have the prescription?)

NEW PRESCRIPTION..... 1 27/

REFILL..... 2

8. Have you taken any of the pills from this prescription yet?

YES...(GO TO Q.12)..... 1 28/

NO...(ASK Q.9)..... 2

9. What is the main reason you haven't started taking this prescription?

CIRCLE ONE.

STILL HAVE PREVIOUS  
PRESCRIPTION...(GO TO Q.11). 1

29/

FELT BETTER/WAS CURED...  
(GO TO Q.12)..... 2

GOT DIFFERENT MEDICATION...  
(GO TO Q.12)..... 3

FORGOT TO TAKE IT...  
(GO TO Q.12)..... 4

DIDN'T WANT TO/DON'T LIKE  
DRUGS...(ASK Q.10)..... 5

WORRIED ABOUT SIDE EFFECTS...  
(ASK Q.10)..... 6

READ PPI...(ASK Q.10)..... 7

OTHER (SPECIFY)...(ASK Q.10).. 8

10. What bothers you about this drug?

CIRCLE ALL THAT APPLY.

A. DON'T LIKE DRUGS/ANTIBIOTICS.. 1

30/

B. SIDE EFFECTS..... 1

31/

C. ALLERGIC REACTIONS..... 1

32/

D. INTERACTIONS WITH OTHER

DRUGS..... 1

33/

E. R'S EXISTING MEDICAL  
CONDITIONS..... 1

34/

F. OTHER (SPECIFY)\_\_\_\_\_ 1

35/

11. INTERVIEWER, CIRCLE ONE:

R MENTIONED LEAFLET..... 1

36/

R DID NOT MENTION LEAFLET..... 2

12. The next set of questions is about the directions you got for taking the erythromycin.

IF R NOT TAKING DRUG SAY: We'd like to ask these questions even though you're not taking the medicine.

IF R OFFERS TO GET CONTAINER SAY: At this point, we'd like to know whatever you remember about the directions, without looking at them.

13. How many pills should you take each time?

A. # PILLS

37/

14. How often should you take the pills?

A. # TIMES PER DAY

38/

OR

B. EVERY  HOURS

39/

15. INTERVIEWER, CIRCLE ONE:

RESPONDENT ANSWERED Q.13-14 FROM MEMORY..... 1

40/

RESPONDENT HAD PRESCRIPTION IN HAND..... 2

16. Should you take the pills around the clock, only when you're awake, whenever you need them, just at bedtime, or what?

AROUND THE CLOCK..... 1

41/

ONLY WHEN AWAKE OR  
MORNING AND EVENING..... 2

WHENEVER R NEEDS THEM..... 3

AT BEDTIME..... 4

OTHER (SPECIFY)\_\_\_\_\_ 5

\_\_\_\_\_)

17. When your doctor gave you the prescription, did the doctor or nurse personally tell you the directions for taking the medicine?

IF R GOT FROM A DENTIST, COUNT AS A DOCTOR.

YES..... 1

42/

NO..... 2

18. When you got the prescription from the pharmacy did the pharmacist personally tell you how to take the medicine?

YES.....	1	43/
NO.....	2	

19. Besides the directions for taking it, did your doctor tell you anything about erythromycin in general or about how it works?

YES....(ASK Q.20).....	1	44/
NO.....(GO TO Q.21).....	2	
DON'T REMEMBER..(GO TO Q.21)..	3	

20. What did your doctor tell you?

CIRCLE ALL THAT APPLY.

A. SAFETY-POSITIVE VIEW.....	1	45/
B. SAFETY-NEGATIVE VIEW.....	1	46/
C. SAFETY-GENERAL.....	1	47/
D. HOW IT WORKS-EFFECTS OF DRUG.....	1	48/
E. HOW TO TAKE IT-DOSAGE DIRECTIONS.....	1	49/
F. REFILLS.....	1	50/
G. SIDE EFFECTS.....	1	51/
H. DRUG INTERACTIONS.....	1	52/
I. GENERAL INFORMATION ABOUT DRUG.....	1	53/
J. OTHER (SPECIFY) _____	1	54/

21. Some doctors like to explain things to their patients and others prefer not to explain as much. How satisfied are you with what your doctor told you about erythromycin? Would you say your doctor:

told you <u>too much</u> about the drug,....	1	55/
told you <u>about the right amount</u> , or..	2	
told you <u>too little</u> ?.....	3	



22. At the time you got the prescription from your doctor, did you ask your doctor any questions about your illness or the drug?

YES..... 1 56/  
NO..... 2

23. Different doctors and pharmacists have different ideas about how medicine should be taken. I'm going to ask about several different things and you may or may not have gotten instructions about any of them. Just tell me what you think is best.  
When are you supposed to take the pills--at mealtime, right after meals, on an empty stomach, or do you not have any information about that?

AT MEALTIME..... 1 57/  
RIGHT AFTER MEALS..... 2  
ON EMPTY STOMACH..... 3  
NOT ON EMPTY STOMACH..... 4  
NO INFORMATION..... 5

24. When you take the pills should they be swallowed whole, should you break them up, does it not matter much either way, or do you not have any information about that?

SWALLOW WHOLE..... 1 58/  
BREAK THEM UP..... 2  
DOESN'T MATTER..... 3  
NO INFORMATION..... 4

25. Should you take the medicine until it is all used up, until you feel better, or do you not have any information about that?

MEDICINE USED UP..... 1 59/  
UNTIL FEEL BETTER..... 2  
NO INFORMATION..... 3

26. Are there any foods or drinks you should not have with these pills, does what you eat or drink not matter, or do you not have any information about that?

THERE ARE FOODS/DRINKS..... 1 60/  
NO FOODS OR DRINKS..... 2  
NO INFORMATION..... 3

27. We'd like to know how much of the erythromycin from this prescription you still have. Could you find the container of pills and count how many pills you have left?

IF R WILL NOT COUNT, PROBE: Based on how many pills you've taken, how many pills would you <u>estimate</u> are left?	A.	ACTUAL COUNT # PILLS LEFT	<input type="text"/> <input type="text"/>	(ASK Q.28)	61-62/	
	ALL USED UP..(GO TO Q.31). 00					
	B.		ESTIMATE # PILLS LEFT...	<input type="text"/> <input type="text"/>	(ENTER 27C)	63-64/
	OTHER RESPONSE...(ENTER 27C AND ASK 28)..... MM					

27C. REASON NO PILL COUNT ENTERED:

- |  |   |     |
|--|---|-----|
| CAN'T FIND/KEPT AT OTHER LOCATION..... | 1 | 65/ |
| HAVEN'T TAKEN ANY YET.....             | 2 |     |
| REFUSED TO COUNT.....                  | 3 |     |
| OTHER (SPECIFY) _____                  | 4 |     |

28. Do you expect to (continue to) take the erythromycin from this prescription?

- |                         |   |     |
|-------------------------|---|-----|
| YES...(GO TO Q.31)..... | 1 | 66/ |
| NO...(ASK Q.29).....    | 2 |     |

29. Why don't you think you'll take the pills?

CIRCLE ALL THAT APPLY.

A. NAUSEA, STOMACH PROBLEMS.....	1	67/
B. ALLERGIC TO DRUG.....	1	68/
C. FUNGUS/YEAST INFECTION.....	1	69/
D. LIVER PROBLEMS.....	1	70/
E. CHANGED DRUGS.....	1	71/
F. DRUG IS NOT HELPING.....	1	72/
G. GOT WELL.....	1	73/
H. OTHER (SPECIFY) _____	1	74/

---

30. INTERVIEWER, CIRCLE ONE:

R MENTIONED LEAFLET.....	1	75/
R DID <u>NOT</u> MENTION LEAFLET.....	2	

31. Did your doctor prescribe erythromycin for you:

because you <u>had</u> some kind of infection...(ASK Q.32).....	1	76/
to <u>prevent</u> an infection from starting...(GO TO Q.36).....	2	
or for some other reason?..(ASK Q.32). What was the reason? _____	3	

---

32. What were all the symptoms you had at the time the doctor gave you this erythromycin prescription?  
IF NAME OF ILLNESS GIVEN ASK:  
What were the symptoms of that?  
LIST ALL SYMPTOMS BELOW.

33. IF ONE SYMPTOM  
CIRCLE 1 WITHOUT  
ASKING. IF MORE THAN  
ONE, ASK: Which of  
these symptoms was  
the erythromycin  
prescribed to help?

(CIRCLE "1" FOR  
SYMPTOMS DRUG IS  
SUPPOSED TO HELP.)

A. _____	<input type="checkbox"/> <input type="checkbox"/>	1	13-15/
B. _____	<input type="checkbox"/> <input type="checkbox"/>	1	16-18/
C. _____	<input type="checkbox"/> <input type="checkbox"/>	1	19-21/
D. _____	<input type="checkbox"/> <input type="checkbox"/>	1	22-24/
E. _____	<input type="checkbox"/> <input type="checkbox"/>	1	25-27/
F. _____	<input type="checkbox"/> <input type="checkbox"/>	1	28-30/

34. INTERVIEWER, HOW MANY SYMPTOMS DID YOU CIRCLE?

ALL OF THOSE LISTED..(ASK Q.35).... 1 31/

SOME OF THOSE LISTED.(ASK Q.35).... 2

NONE OF THOSE LISTED.(GO TO Q.39).. 3

35. How (are these symptoms/is the symptom) for you now? (Are the symptoms/Is the symptom) the erythromycin was prescribed for:

much better,..... 1 32/

somewhat better,..... 2

about the same,..... 3

somewhat worse,..... 4

or much worse?..... 5

SOME BETTER, SOME WORSE..... 6

(GO TO Q. 38)

36. What kind of infection was erythromycin prescribed to prevent?

_____	<input type="checkbox"/> <input type="checkbox"/>	33-34/
_____	<input type="checkbox"/> <input type="checkbox"/>	35-36/

37. How well did erythromycin work in preventing infection for you?  
Would you say it was:

very effective,..... 1 37/  
somewhat effective,..... 2  
not very effective, or..... 3  
not effective at all?..... 4  
HAVE NOT TAKEN DRUG..... 5

38. Overall, how is your health now, compared to the time when you got the  
erythromycin? Is it:

much better,..... 1 38/  
somewhat better,..... 2  
about the same,..... 3  
somewhat worse,..... 4  
or much worse?..... 5  
SOME WAYS BETTER, SOME WAYS  
WORSE..... 6

39. When you got this prescription did your doctor say there might be  
side effects from it, that side effects were not likely, or did the  
doctor not mention side effects at all?

MIGHT BE SIDE EFFECTS...(ASK Q.40).... 1 39/  
SIDE EFFECTS NOT LIKELY.(GO TO Q.41).. 2  
DID NOT MENTION THEM....(GO TO Q.41).. 3

40. What side effects did the doctor tell you about?

NONE..... 000 }  
A. \_\_\_\_\_ } 40-42/  
B. \_\_\_\_\_ } 43-45/  
C. \_\_\_\_\_ } 46-48/  
D. \_\_\_\_\_ } 49-51/  
E. \_\_\_\_\_ } 52-54/

41. Now I'm going to read you a list of physical problems people sometimes have. For each one, please tell me if you've had the problem or not since the time when you got the erythromycin prescription, (even though you haven't been taking it). CHECK EACH SYMPTOM IN Q.41A. CIRCLE 4 AND SKIP THOSE ALREADY MENTIONED IN Q.32. IF R IS TAKING DRUG, FOR EACH SYMPTOM R HAD ASK Q.41B. ASK 41A AND 41B FOR EACH SYMPTOM BEFORE GOING ON TO THE NEXT SYMPTOM.

41A. Have you had (any) _____ ?				41B. Do you think the _____ (is/are) due to your general condition, the erythromycin, or both?			
IN Q.32	YES	NO	DK	CONDITION	DRUG	BOTH	DK
↓	↓ (ASK 41B OR NEXT SYMPTOM)	↓ (NEXT SYMPTOM OR Q.42)	↓	↓ NOT TAKING DRUG	↓ (NEXT SYMPTOM OR Q.42)	↓	↓

(1) Upset stomach	4	1	2	7	4	1	2	3	7	55-56/
(2) Diarrhea	4	1	2	7	4	1	2	3	7	57-58/
(3) Nosebleeds	4	1	2	7	4	1	2	3	7	59-60/
(4) Skin rash	4	1	2	7	4	1	2	3	7	61-62/
(5) Stomach cramps	4	1	2	7	4	1	2	3	7	63-64/
(6) Muscle spasms or twitches	4	1	2	7	4	1	2	3	7	65-66/
(7) Swollen ankles when you wake up	4	1	2	7	4	1	2	3	7	67-68/
(8) Dry mouth	4	1	2	7	4	1	2	3	7	69-70/
(9) Yeast or fungus-type infection	4	1	2	7	4	1	2	3	7	71-72/
(10) Bleeding or soreness of the mouth	4	1	2	7	4	1	2	3	7	73-74/

42. INTERVIEWER, CHECK Q.41B AND CIRCLE ONE:

ANY 2's OR 3's CIRCLED...  
(ASK Q.43)..... 1 13/  
  
NO 2's OR 3's CIRCLED...  
(GO TO Q.44B)..... 2

43. You've been having some problem(s) caused by the erythromycin. If you take it in the future do you think you'll have these again? Would you say it's:

very likely,..... 1 14/  
somewhat likely,..... 2  
a 50-50 chance,..... 3  
somewhat unlikely,..... 4  
or very unlikely?..... 5  
(ASK Q.44A)

44A. How much did it bother you to have some of these problems when you were taking erythromycin? Did it bother you:

44B. How much would it bother you to have some of the problems I just asked about when you take erythromycin? Do you think it would bother you:

a lot,..... 1 15/  
some,..... 2  
a little,..... 3  
or not at all?..... 4

45. How many times in the past year have you had the same (illness/need to prevent infection) you had when the erythromycin was prescribed?

# TIMES 


 } 16-17/  
FREQUENT OR CHRONIC PROBLEM... 99 }

46. INTERVIEWER, CHECK Q.7 AND CIRCLE ONE:

THIS IS A NEW PRESCRIPTION...  
(ASK Q.47)..... 1 18/  
  
THIS IS A REFILL...  
(GO TO Q.48)..... 2

47. Is this the first prescription for erythromycin you've ever had?

YES...(GO TO Q.49)..... 1 19/  
NO...(ASK Q.48)..... 2

48. Counting all prescriptions and refills, how many erythromycin prescriptions have you had in the past year?

# PRESCRIPTIONS

--	--

20-21/

49. Have you ever had a serious side effect or bad reaction from:

YES NO DK

A. erythromycin?

1 2 7

22/

B. any other antibiotic, such as penicillin or ampicillin?

1 2 7

23/

50. Who first mentioned to you the possibility of taking erythromycin (for this illness?) Was it you, was it your doctor, or was it someone else?

IF SOMEONE ELSE: Was that person a member of your family?

CIRCLE ONE.

RESPONDENT..... 1

24/

DOCTOR..... 2

RELATIVE OF R..... 3

OTHER..... 4

DON'T RECALL..... 5

51. (For this illness,) did you see the doctor before you got the prescription or was the erythromycin prescribed without your doctor seeing you?

R SAW DOCTOR..... 1

25/

R DID NOT SEE DOCTOR..... 2

52. How long a period of time was there between the time you (saw/spoke with) your doctor and the time you got the prescription from the pharmacy?

COUNT "NEXT DAY" AS 02, ETC.

A. SAME DAY.... 01

# DAYS

--	--

26-27/

B. # WEEKS

--	--

28-29/



53. Does the doctor who gave you this prescription usually treat you at:

a hospital,..... 1 30/  
a clinic,..... 2  
a private office,..... 3  
or someplace else?..... 4  
(Where?) \_\_\_\_\_

NEVER SAW DOCTOR AT ALL..... 5

54. Since you got this prescription from the pharmacy, have you talked to the doctor about the erythromycin or your illness either by phone or in person? IF YES: How many times?

HAVE NOT TALKED WITH DOCTOR...  
(GO TO Q.56)..... 00 }

TALKED # TIMES  
(ASK Q55)

31-32/

55. What kinds of things did you talk with the doctor about?  
PROBE: What else?  
CIRCLE ALL THAT APPLY.

A. SAFETY OF DRUG..... 1 33/  
B. HOW IT WORKS, EFFECTS  
OF DRUGS..... 1 34/  
C. HOW TO TAKE IT, DOSAGE  
DIRECTIONS..... 1 35/  
D. REFILLS..... 1 36/  
E. SIDE EFFECTS..... 1 37/  
F. DURATION OF DRUG TREATMENT.... 1 38/  
G. GENERAL INFO ABOUT DRUG..... 1 39/  
H. OTHER (SPECIFY)..... 1 40/

56. Since you got this prescription, have you talked to the pharmacist about the erythromycin or your illness -- by phone or in person?

YES...(ASK Q.57)..... 1 41/  
NO...(GO TO Q.58)..... 2

57. What kinds of things did you talk with the pharmacist about?

PROBE: What else?

CIRCLE ALL THAT APPLY.

- |  |   |     |
|--|---|-----|
| A. SAFETY OF DRUG.....                       | 1 | 42/ |
| B. EFFECTS OF DRUG, HOW<br>IT WORKS.....     | 1 | 43/ |
| C. HOW TO TAKE IT, DOSAGE<br>DIRECTIONS..... | 1 | 44/ |
| D. REFILLS.....                              | 1 | 45/ |
| E. SIDE EFFECTS.....                         | 1 | 46/ |
| F. DURATION OF DRUG TREATMENT....            | 1 | 47/ |
| G. GENERAL INFO ABOUT DRUG.....              | 1 | 48/ |
| H. OTHER (SPECIFY).....                      | 1 | 49/ |

58. INTERVIEWER, CHECK Q.8 AND CIRCLE ONE:

R HAS TAKEN DRUG (ASK Q.59)..... 1 50/

R HAS NOT TAKEN DRUG (GO TO Q.62)..... 2

59. Now I'd like to ask a few questions about your experience with taking erythromycin. Many people don't take every dose of the medicine right on time because they can't for some reason or they forget. Were there any doses of erythromycin you missed or took late?

YES...(ASK Q.60)..... 1 51/

NO...(GO TO Q.62)..... 2

STOPPED TAKING IT (GO TO Q.61)..... 3

60. How many times was the medicine taken late?

# TIMES	<input type="text"/>	<input type="text"/>	} 52-53/
NEVER.....	00		

61. How many doses did you miss completely?

# DOSES	<input type="text"/>	<input type="text"/>	} 54-55/
NONE.....	00		

62. If you (did) forget to take a pill, what is the best thing to do?  
Is it best to:

<u>wait</u> and take it with your next pill,.....	1	56/
take it right away and take your next pill a little later than usual,.....	2	
or skip the pill entirely?.....	3	

63. (Based on your own experience), how successful do you think erythromycin usually is in treating infections? Would you say it:

always works,.....	1	57/
usually works,.....	2	
sometimes works,.....	3	
usually <u>doesn't</u> work.....	4	
or <u>never</u> works?.....	5	

64. How do you think erythromycin works? Does it mainly work by:

PROBE: From what you've read or heard, what do you think?

killing bacteria,.....	1	58/
preventing bacteria from multiplying,.....	2	
or both?.....	3	

65. What kinds of illnesses would erythromycin help? Do you think it would or would not help:

	WOULD HELP	WOULD NOT HELP	DON'T KNOW	
A. an ear infection?	1	2	3	59/
B. a common cold?	1	2	3	60/
C. pneumonia?	1	2	3	61/
D. high fever caused by a virus?	1	2	3	62/

66. I'm going to read you a list of several physical conditions people sometimes have. Based on whatever you've read or heard about erythromycin, I'd like to know if you think there would be any special problem taking erythromycin with each condition. The first is heart disease. Would there be any special problem with taking erythromycin for someone:

	YES	NO	DON'T KNOW	
A. with heart disease?	1	2	3	63/
B. who is pregnant or nursing a baby?	1	2	3	64/
C. who has liver trouble?	1	2	3	65/
D. who has frequent headaches?	1	2	3	66/
E. who is taking medicine for asthma?	1	2	3	67/
F. who is allergic to penicillin?	1	2	3	68/

67. From everything you know, do you think the side effects from erythromycin are:

a very serious problem,.....	1	69/
a serious problem,.....	2	
a small problem,.....	3	
or no problem at all?.....	4	

68. What side effects could people get from erythromycin?

	NONE.....	000				
A.	_____	<table border="1"><tr><td></td><td></td><td></td></tr></table>				13-15/
B.	_____	<table border="1"><tr><td></td><td></td><td></td></tr></table>				16-18/
C.	_____	<table border="1"><tr><td></td><td></td><td></td></tr></table>				19-21/
D.	_____	<table border="1"><tr><td></td><td></td><td></td></tr></table>				22-24/
E.	_____	<table border="1"><tr><td></td><td></td><td></td></tr></table>				25-27/

69. Now I would like to ask you a few questions about the leaflet that may have come with your prescription. Do you remember a leaflet that came with your prescription?

YES...(GO TO Q.71)..... 1 28/  
NO...(ASK Q.70)..... 2

70. The leaflet was white and it may have been given to you with the prescription. Do you remember getting something like this?

YES...(ASK Q.71)..... 1 29/  
NO...(GO TO Q.88)..... 2

71. Did you read it before taking the medicine?

YES...(GO TO Q.73)..... 1 30/  
NO...(ASK Q.72)..... 2  
DON'T KNOW...(ASK Q.72)..... 3

72. Did you read it later?

YES...(ASK Q.73)..... 1 31/  
NO...(GO TO Q.88)..... 2

73. After the first time you read it, did you ever go back and read any of it again?

YES...(ASK Q.74)..... 1 32/  
NO...(GO TO Q.75)..... 2

74. Why did you read it again?  
CIRCLE ALL THAT APPLY.

A. KNEW INTERVIEWER WOULD CALL.....	1	33/
B. SAFETY OF DRUG.....	1	34/
C. DOSAGE DIRECTIONS.....	1	35/
D. SIDE EFFECT.....	1	36/
E. DRUG/FOOD/DRINK INTERACTIONS.....	1	37/
F. OTHER (SPECIFY).....	1	38/

---

75. Did you keep the leaflet, did you throw it away, or what?

KEPT IT...(ASK Q.76).....	1	39/
THREW IT AWAY...(GO TO.79)....	2	
GAVE IT TO SOMEONE ELSE... (GO TO Q.80).....	3	
OTHER (SPECIFY)..(GO TO Q.79)..	4	

---

76. Where do you keep the leaflet? For example, is it on a shelf in a drawer, or what?

IF "MEDICINE CHEST": Is it on the shelf or on the door?

ON A SHELF.....	1	40/
IN A DRAWER.....	2	
ON A TABLE, DESK, COUNTER TOP.	3	
HANGING ON WALL, DOOR.....	4	
OTHER (SPECIFY).....	5	

---

DON'T KNOW..... 7

77. What room is it in?

BATHROOM.....	1	41/
BEDROOM.....	2	
KITCHEN.....	3	
OTHER ROOM.....	4	

78. Is it usually kept with the drug or are the leaflet and the drug kept in different places?

WITH DRUG..... 1 42/

NOT WITH DRUG..... 2

79. Did anyone else read the leaflet from your prescription?

YES...(ASK Q.80)..... 1 43/

NO...(GO TO Q.81)..... 2

80. Who else read it?  
CIRCLE ALL THAT APPLY.

A. SPOUSE OF R..... 1 44/

B. OTHER FAMILY MEMBER..... 1 45/

C. FRIEND..... 1 46/

D. OTHER (SPECIFY)..... 1 47/

81. Did the leaflet say anything you didn't know before you read it or was it mostly information you already had?

NEW INFORMATION..... 1 48/

MOSTLY INFORMATION ALREADY  
HAD..... 2

82. In your opinion, how easy or hard to read would this leaflet be for most people? Would it be:

very easy,.....	1	49/
fairly easy,.....	2	
fairly hard, or.....	3	
very hard?.....	4	

83. About how many years of school do you think most people would need to be able to read and understand the leaflet?

NOTE: GRADE SCHOOL..... 08  
 HIGH SCHOOL..... 12  
 COLLEGE (B.A.,B.S.)... 16  
 MORE THAN COLLEGE..... 18

NUMBER	<input type="text"/>	<input type="text"/>
OF YEARS	<input type="text"/>	<input type="text"/>
DON'T KNOW....	77	

50-51/

84. Did anything you read in the leaflet worry you or was most of it simply information?

WORRIED R...(ASK Q.85).....	1	52/
DIDN'T WORRY R... (GO TO Q.86).....	2	

85. What part of the leaflet made you worry?

\_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_ (OFFICE USE)

_____	A.	<input type="text"/>	<input type="text"/>	B.	<input type="text"/>	<input type="text"/>
_____			/			

53-56/

86. On the whole, would you say the leaflet did or did not help you to understand more about erythromycin?

DID HELP.....	1	57/
DID <u>NOT</u> HELP.....	2	



87. Would you say it did or did not help you to:

A. Follow the doctor's orders about erythromycin?

DID HELP..... 1 58/

DID NOT HELP..... 2

B. Understand the effects of erythromycin?

DID HELP..... 1 59/

DID NOT HELP..... 2

C. Know when to take erythromycin?

DID HELP..... 1 60/

DID NOT HELP..... 2

88. CHECK Q.7 AND Q.31 AND CIRCLE ONE:

R TOOK DRUG TO CURE INFECTION...

(ASK Q.89)..... 1 61/

R TOOK DRUG TO PREVENT INFECTION...

(GO TO Q.90)..... 2

R HAS NOT TAKEN DRUG...

(GO TO Q.95)..... 3

89. Before you started taking erythromycin, how would you describe your infection? Would you say it made you:

extremely uncomfortable,..... 1 62/

moderately uncomfortable,..... 2

slightly uncomfortable, or.... 3

not uncomfortable at all?..... 4

90. Before you started taking the erythromycin, how successful did you think it would be in (treating/preventing) your infection? Did you think it would be:

completely successful,..... 1 63/  
very successful,..... 2  
somewhat successful,..... 3  
or not very successful,..... 4

91. When a person has an infection of the type you (just had/were trying to prevent) and doesn't take any medicine for it, how serious could it get to be? Would you say without treating the infection it could get to be:

extremely serious,..... 1 64/  
moderately serious,..... 2  
somewhat serious, or..... 3  
not serious at all?..... 4

92. The next time you (get symptoms like those you just had/need to prevent the same kind of infection), do you think you would want to take erythromycin?

IF R SAYS "IF DR. SAYS SO" PROBE: What would you think about taking it in the future (for these symptoms?)

YES..... 1 65/  
NO..... 2

93. Overall, do you feel that any benefits you got from taking erythromycin were:

less than you expected,..... 1 66/  
pretty much what you expected, or.... 2  
greater than you expected?..... 3

94. Overall, do you feel that any problems you had from taking erythromycin were:

more serious than you expected,..... 1 67/  
pretty much what you expected, or.... 2  
less serious than you expected?..... 3  
HAD NO PROBLEMS..... 4

95. Now we're going to do something different. We are interested in what certain words mean to people. I'm going to read some words to you. I want you to listen to each word, think about what it means for a minute, and then tell me as exactly as you can what it means to you. Some of these words may be unfamiliar to you, but if you have any idea what a word means, please take a guess. Let's start with chronic. What does chronic mean to you?

RECORD RESPONSES VERBATIM. CONTINUE WITH WORDS  
B - H, SAYING EACH WORD ALOUD AND RECORDING  
RESPONSES.

- A. CHRONIC \_\_\_\_\_ ☐ 68/  
\_\_\_\_\_
- B. VACCINE \_\_\_\_\_ ☐ 69/  
\_\_\_\_\_
- C. CARCINOGEN \_\_\_\_\_ ☐ 70/  
\_\_\_\_\_
- D. PULMONARY \_\_\_\_\_ ☐ 71/  
\_\_\_\_\_
- E. GLUCOSE \_\_\_\_\_ ☐ 72/  
\_\_\_\_\_
- F. PLACEBO \_\_\_\_\_ ☐ 73/  
\_\_\_\_\_
- G. MALPRACTICE \_\_\_\_\_ ☐ 74/  
\_\_\_\_\_

Now I'd like to ask you some questions about your background. This information will help us compare the opinions of different groups of people.

96. Just so I can be sure, are you male or female?

MALE.....	1	75/
FEMALE.....	2	

97. Are you married and living with your (husband/wife), widowed, divorced, separated, or have you never been married?  
IF "SINGLE" ASK: Is that divorced, separated, or never married?

MARRIED AND LIVING WITH SPOUSE.....	1	76/
WIDOWED.....	2	
DIVORCED.....	3	
SEPARATED.....	4	
NEVER MARRIED.....	5	
SINGLE.....	6	

98. CHECK Q.97 AND CIRCLE ONE:

R IS MARRIED AND LIVING WITH SPOUSE (Q.97 = 1)...		
<u>ASK</u> QUESTIONS ABOUT SPOUSE.....	1	77/
R HAS OTHER MARITAL STATUS (Q.97 = 2-6)...		
<u>DO NOT</u> ASK QUESTIONS ABOUT SPOUSE.....	2	

99. How old were you on your last birthday? IF SPOUSE APPLIES: How old was your (husband/wife) on (his/her) last birthday?

A. ENTER RESPONDENT AGE

13-14/

B. ENTER SPOUSE AGE

15-16/

100. What is the highest grade or year of regular school or college you ever finished and got credit for? IF SPOUSE APPLIES: What is the highest grade or year of regular school or college your (husband/wife) finished and got credit for?

A. ENTER RESPONDENT GRADE CODE

17-18/

B. ENTER SPOUSE GRADE CODE.

19-20/

GRADE CODES	
No formal schooling.....	00
ELEMENTARY	
1st grade.....	01
2nd grade.....	02
3rd grade.....	03
4th grade.....	04
5th grade.....	05
6th grade.....	06
7th grade.....	07
8th grade.....	08
HIGH SCHOOL	
1st year (9th grade).....	09
2nd year (10th grade).....	10
3rd year (11th grade).....	11
4th year (H.S. Diploma, GED, 12th grade).....	12
COLLEGE	
1 year.....	13
2 years.....	14
3 years.....	15
4 years.....	16
POST COLLEGE	
1 year.....	17
2 years.....	18
3 years.....	19
4 years +.....	20

101. IF R OR SPOUSE COMPLETED GRADE 8 OR MORE, ASK: What is the highest diploma or degree (you have?/your husband has?/your wife has?). CIRCLE ONE CATEGORY EACH FOR R AND SPOUSE.

	A. RESPONDENT	B. SPOUSE
NONE.....	00	00
HIGH SCHOOL DIPLOMA.....	01	01
ASSOCIATE, e.g., AA.....	02	02
BA, BS.....	03	03
MA, MS, MPA.....	04	04
MD, LLB, PhD, JD.....	05	05
OTHER.....	06	06
SPECIFY: _____		
DOES NOT APPLY.....	NN	NN

21-24/

102. ASK Q.102-106, FIRST FOR RESPONDENT THEN FOR SPOUSE.

FOR RESPONDENT: What is your current employment status--are you working full-time, working part-time, in school, retired, disabled, keeping house, unemployed, or something else?

FOR SPOUSE: What is your (husband's/wife's) current employment status--is (he/she) working full-time, working part-time, in school, retired, disabled, keeping house, unemployed, or something else?

	A. RESPONDENT	B. SPOUSE	
WORKING FULL-TIME...(GO TO Q.104).....	1	1	25-26/
WORKING PART-TIME...(GO TO Q.104).....	2	2	
IN SCHOOL...(ASK Q.103).....	3	3	
RETIRED...(GO TO Q.104).....	4	4	
DISABLED...(ASK Q.103).....	5	5	
KEEPING HOUSE...(ASK Q.103).....	6	6	
UNEMPLOYED...(ASK Q.103).....	7	7	
OTHER...(ASK Q.103).....	8	8	

SPECIFY: \_\_\_\_\_

103. FOR RESPONDENT: Have you ever been employed?

FOR SPOUSE: Has (he/she) ever been employed?

	A. RESPONDENT	B. SPOUSE	
YES...(ASK Q.104-106).....	1	1	27-28/
NO...(GO TO SPOUSE OR Q.107).....	2	2	

104. FOR RESPONDENT: What kind of business or industry (do/did) you work in--what (does/did) the place you work(ed) at make or do?

FOR SPOUSE: What kind of business or industry (does/did) your (husband/wife) work in--what (does/did) the place (he/she) works(ed) at make or do?

105. FOR RESPONDENT: What (is/was) your job title? What kind of work (are/were) you doing?

FOR SPOUSE: What (is/was) (his/her) job title? What kind of work (is/was) (he/she) doing?

106. FOR RESPONDENT: What (are/were) your most important activities or duties?

FOR SPOUSE: What (are/were) (his/her) most important activities or duties?

(OFFICE USE)  
[ ] [ ] [ ] [ ] [ ] [ ]

(OFFICE USE)

[ ] [ ] [ ]

(OFFICE USE)  
[ ] [ ] [ ] [ ] [ ] [ ]

(OFFICE USE)

[ ] [ ] [ ]

29-40/

41-46/

107. What do you consider to be your own main racial or ethnic group?  
Would you say it is:

American Indian or Alaskan native.....	1	47/
Asian or Pacific islander.....	2	
Black, but not of Hispanic origin.....	3	
Hispanic, or.....	4	
White, but not of Hispanic origin?.....	5	
OTHER (SPECIFY).....	6	

108. The last few questions are about your opinions. I'll read a statement to you and you can tell me if you agree or disagree. Here's the first statement. READ 108A. Would you say you agree or disagree?

	AGREE	DISAGREE	NOT SURE	
A. I'm as healthy as most people I know.	1	3	2	48/
B. There is not much a person can do to prevent illness.	1	3	2	49/
C. When I'm sick I try to just keep going as usual.	1	3	2	50/
D. A person should take medicine only as a last resort.	1	3	2	51/
E. I always follow my doctor's instruc- tions even if I don't understand them.	1	3	2	52/

That's the end of the interview. Now I need to get your address so I can send you the payment for being a participant.

FILL IN NAME AND ADDRESS ON CONTACT FOLDER.

You'll receive your payment in a week or so. We'll also send you a short questionnaire to fill out, if that's OK with you. It's a few more questions like the last ones I just asked. You'll get a stamped envelope to return it in and we'd appreciate your sending it back as soon as possible.

IF PPI SAY:

Before I hang up, I want to tell you that one of the reasons for the interview was to see whether the leaflets were written so that people could remember them. When I asked about side effects and reasons for not taking the drug I read you a list of several different side effects and things people should be careful about in taking the drug. Some of the things I read you were real side effects or real things to be careful about and some just sounded real, but weren't. If you have any questions about erythromycin or your symptoms please (look at the leaflet again or) talk with your pharmacist or doctor.

IF NO PPI SAY:

Before I hang up, I want to tell you that one of the reasons for the interview was to see whether people could obtain good information about prescription drugs. When I asked about side effects and reasons for not taking the drug I read you a list of several different side effects and things to be careful about. Some of the things I read you were real side effects or real things to be careful about, and some just sounded real, but weren't. If you have any questions about Erythromycin please talk with your pharmacist or doctor.

Thank you very much for your help. I've enjoyed talking with you.

TIME ENDED   :   53-56/  
AM..... 1 57/  
PM..... 2



Appendix C

DALMANE TELEPHONE SURVEY

OMB# 57-S 78006

Expires 12/81

VERSION - 10/15/79

1-10/

CASE #

--	--	--	--	--	--	--	--

13-16/

PRESCRIPTION DRUG  
INFORMATION STUDY

TELEPHONE INTERVIEW: DALMANE

CARD 01

11-12/



TIME BEGAN:

		:		
--	--	---	--	--

17-20/

AM..... 1

21/

PM..... 2

Hello, I'm \_\_\_\_\_, calling from the Rand Corporation in Santa Monica. We're doing a study for the U.S. Department of Health, Education, and Welfare about prescription drugs. When you picked up a prescription from (NAME OF PHARMACY) you signed an authorization form that let the pharmacy give us your name to be part of this study. I'd like to do an interview with you now, over the phone, if you have time.

1. Our record from the pharmacy shows you received a prescription drug on (DATE). Do you remember the name of the drug?  
IF "MORE THAN ONE": Tell me all the prescriptions you got that day.  
IF "SLEEPING PILL": Do you know the name of the particular sleeping pill?

NAMES DALMANE OR FLURAZEPAM...

(GO TO Q.6)..... 1

22/

"SLEEPING PILL" ONLY

(ASK Q.2)..... 2

NAMES ONLY OTHER DRUGS...

(ASK Q.2)..... 3

DOESN'T KNOW NAME...(ASK Q.2). 4

2. Did you receive a prescription for dalmane? If "NO" OR UNSURE PROBE:  
This drug is also called flurazepam.

SAID "SLEEPING PILL" IN Q.1,

CONFIRMS IT'S DALMANE...

(GO TO Q.7)..... 1

23/

NOW REMEMBERS IT'S DALMANE...

(GO TO Q.6)..... 2

DIDN'T RECEIVE OR NOT SURE...

(ASK Q.3)..... 3

- 3... This drug was in the form of capsules. They are either orange and white or red and white. It cost (AMOUNT).

RECEIVED DALMANE....  
(GO TO Q.6)..... 1 24/  
  
DIDN'T RECEIVE OR UNSURE..... 2

4. This drug is usually prescribed as a sleeping pill.

RECEIVED DALMANE....  
(GO TO Q.7)..... 1 25/  
  
DIDN'T RECEIVE OR UNSURE...  
(READ Q.5)..... 2

5. Since we're not sure you received dalmane I'd like to check our records again before we do the interview. This is not something you should worry about. Occasionally we have small mix-ups. I'll check it carefully and call you back to tell you what I find out.

TERMINATE INTERVIEW AND SEE YOUR SUPERVISOR.

6. What kind of a drug is dalmane? Would you say it's:

an antihistamine,..... 1 26/  
an hypnotic,..... 2  
an antibiotic,..... 3  
or something else?  
SLEEPING PILL..... 4  
BENZODIAZEPINE..... 5  
OTHER (SPECIFY)..... 6  
  
DON'T KNOW..... 7

7. Was this prescription a new prescription or a refill?  
(PROBE: Did your doctor give you a prescription or call an order into the pharmacy for the pills you received on (DATE), or did the pharmacy already have a prescription?)

NEW PRESCRIPTION..... 1 27/  
REFILL..... 2

8. Have you taken any of the pills from this prescription yet?

YES....(GO TO Q.12)..... 1 28/  
NO....(ASK Q.9)..... 2  
  
HAS TAKEN PREVIOUSLY...  
(ASK Q.9)..... 3

9. What is the main reason you haven't taken any of them?

CIRCLE ONE.

STILL USING UP OLD SLEEPING PILL PRESCRIPTION...(GO TO Q.12).....	1	29/
DIDN'T NEED THEM(GO TO Q.12).....	2	
GOT DIFFERENT MEDICATION..(GO TO Q.12)	3	
FORGOT TO TAKE THEM..(GO TO Q.12).....	4	
DISCOVERED SHOULDN'T TAKE THEM... (ASK Q.10).....	5	
DIDN'T WANT TO/DOESN'T LIKE DRUGS... (ASK Q.10).....	6	
WORRIED ABOUT BAD EFFECTS OF DRUG....(ASK Q.10).....	7	
READ PPI...(ASK Q.10).....	8	
OTHER (SPECIFY)...(ASK Q.10).....	9	

---

10. What bothers you about this drug?

CIRCLE ALL THAT APPLY. A. HANGOVER, DROWSINESS.....	1	30/
B. POSSIBLE DEPENDENCE.....	1	31/
C. INTERACTIONS WITH OTHER DRUGS.....	1	32/
D. R'S EXISTING MEDICAL CONDITIONS.....	1	33/
E. SIDE EFFECTS.....	1	34/
F. OTHER (SPECIFY)_____	1	35/

---

11. INTERVIEWER CIRCLE ONE:

R MENTIONED LEAFLET.....	1	36/
R DID NOT MENTION LEAFLET.....	2	

12. The next set of questions is about the directions you got for taking dalmane.  
IF R NOT TAKING DRUG: We'd like to ask them even though you're not taking it.  
IF R OFFERS TO GET CONTAINER SAY: At this point we'd like to know whatever you remember about the directions without looking at them.
13. In your prescription, how many milligrams of dalmane are in each capsule?
- |                 |   |     |
|-----------------|---|-----|
| 15 MG.....      | 1 | 37/ |
| 30 MG.....      | 2 |     |
| OTHER MG.....   | 3 |     |
| DON'T KNOW..... | 7 |     |
14. How many capsules can you take each time you take dalmane?
- A. # OF PILLS EACH TIME   38/
- OR
- B. CHOICE OF  OR  39-40/  
EITHER
15. INTERVIEWER, CIRCLE ONE:
- |  |   |     |
|--|---|-----|
| RESPONDENT ANSWERED Q.13-14 FROM MEMORY..... | 1 | 41/ |
| RESPONDENT HAD PRESCRIPTION IN HAND.....     | 2 |     |
16. If you haven't taken dalmane for a week or so and you take a pill, how long are you likely to sleep?
- |  |    |        |
|--|----|--------|
| LESS THAN ONE HOUR.....                              | 00 | 42-43/ |
| # OF HOURS <input type="text"/> <input type="text"/> |    |        |
17. When do you take the dalmane? Do you take it:
- |  |   |     |
|--|---|-----|
| every night before you go to bed,...(GO TO Q.19).....            | 1 | 44/ |
| or only on nights when you're unable to sleep?...(ASK Q.18)..... | 2 |     |

18. How do you decide whether to take a pill or not? (PROBE: Do you decide before or after you've gone to bed?)

KNOW IN ADVANCE WHEN WON'T BE  
ABLE TO SLEEP; TAKE PILL.... 1 45/

TRY TO SLEEP FIRST, THEN  
TAKE PILL..... 2

MENTIONS BOTH..... 3

OTHER (SPECIFY)\_\_\_\_\_ 4

\_\_\_\_\_  
\_\_\_\_\_

(GO TO Q. 20)

19. Did your doctor tell you that you should take a pill every night or is that something you've learned from your own experience?

DOCTOR'S INSTRUCTIONS..... 1 46/

R'S OWN EXPERIENCE..... 2

20. If you have taken the drug but are still having trouble going to sleep, do you take another pill that night or not?

YES...(ASK Q.21)..... 1 47/

NO....(GO TO Q.23)..... 2

21. How long do you usually wait before taking another pill?

HALF AN HOUR OR LESS..... 1 48/

31-60 MINUTES..... 2

MORE THAN AN HOUR..... 3

22. Did your doctor tell you that you should take another pill or is that something you've learned from your own experience?

DOCTOR'S INSTRUCTIONS..... 1 49/

R'S EXPERIENCE..... 2

23. We'd like to know how much of the dalmane from this prescription you still have. Could you find the container of pills and count how many pills you have left?

IF R WILL NOT COUNT,  
PROBE: Based on how  
many pills you've  
taken, how many pills  
would you estimate  
are left?

A. ACTUAL COUNT  
# PILLS LEFT

(GO TO Q.24)

50-51/

ALL USED UP..(GO TO Q.28).... 00

B. ESTIMATED # PILLS LEFT  
(ANSWER Q.23C AND  
ASK Q.24).....

52-53/

OTHER RESPONSE...(ANSWER 23C  
AND ASK Q.24)..... MM

23C. REASON NO EXACT PILL COUNT ENTERED:

CAN'T FIND/KEPT AT OTHER  
LOCATION..... 1

54/

HAVEN'T TAKEN ANY YET..... 2

REFUSED TO COUNT..... 3

OTHER (SPECIFY)..... 4

24. Do you expect to (continue to) take the dalmane from this prescription?

YES...(ASK Q.25)..... 1

55/

NO...(GO TO Q.26)..... 2

DON'T KNOW...(GO TO Q.26)..... 3

25. How long do you think it will take you to use up all the pills left in this current prescription? (PROBE: How many days or weeks?)

A. NUMBER OF DAYS

56-57/

B. NUMBER OF WEEKS

58-59/

C. NUMBER OF MONTHS

60-61/

(GO TO Q.28)

-7-

26. Why don't you think you'll take the pills?

CIRCLE ALL THAT APPLY.

A. HANGOVER, DROWSINESS.....	1	62/
B. POSSIBLE DEPENDENCE.....	1	63/
D. INTERACTIONS WITH OTHER DRUGS.....	1	64/
D. BAD REACTION/SIDE EFFECTS.....	1	65/
E. SLEEPING PROBLEM OVER.....	1	66/
F. OTHER (SPECIFY) _____	1	67/

---

27. INTERVIEWER CIRCLE ONE:

R MENTIONED LEAFLET.....	1	68/
R DID NOT MENTION LEAFLET.....	2	

28. Can this prescription be refilled (again) without talking to your doctor?

YES.....	1	69/
NO.....	2	
DON'T KNOW.....	3	

29. When this prescription runs out (with no more refills), do you think the doctor will give you a new prescription for dalmane if you want one, will the doctor want to talk about it first, will the doctor not give you a new prescription, or what?

WILL GIVE NEW PRESCRIPTION....	1	70/
WILL TALK ABOUT IT.....	2	
WON'T GIVE NEW PRESCRIPTION...	3	
DONT KNOW.....	7	
OTHER (SPECIFY).....	4	

---

---

30. Did the pharmacist where you got the prescription filled tell you anything about the dalmane or how to take it?

YES....(ASK Q.31).....	1	71/
NO.....(GO TO Q.32).....	2	



31. What did the pharmacist tell you?

CIRCLE ALL THAT APPLY.

- |  |   |     |
|--|---|-----|
| A. SAFETY - POSITIVE VIEW.....           | 1 | 13/ |
| B. SAFETY - NEGATIVE VIEW.....           | 1 | 14/ |
| C. SAFETY - GENERAL.....                 | 1 | 15/ |
| D. HOW IT WORKS, EFFECTS OF DRUG.....    | 1 | 16/ |
| E. HOW TO TAKE IT, DOSAGE DIRECTIONS.... | 1 | 17/ |
| F. REFILLS.....                          | 1 | 18/ |
| G. SIDE EFFECTS (INC. DROWSINESS).....   | 1 | 19/ |
| H. DEPENDENCE.....                       | 1 | 20/ |
| I. ALCOHOL/DRUG INTERACTIONS.....        | 1 | 21/ |
| J. GENERAL INFO ABOUT DRUG.....          | 1 | 22/ |
| K. OTHER (SPECIFY) _____                 | 1 | 23/ |

32. Did your doctor personally tell you anything about dalmane in general or about how it works?

- |                          |   |     |
|--------------------------|---|-----|
| YES....(ASK Q.33).....   | 1 | 24/ |
| NO.....(GO TO Q.34)..... | 2 |     |

33. What did your doctor tell you?

CIRCLE ALL THAT APPLY.

A. SAFETY - POSITIVE VIEW.....	1	25/
B. SAFETY - NEGATIVE VIEW.....	1	26/
C. SAFETY - GENERAL.....	1	27/
D. HOW IT WORKS, EFFECTS OF DRUG.....	1	28/
E. HOW TO TAKE IT, DOSAGE DIRECTIONS....	1	29/
F. REFILLS.....	1	30/
G. SIDE EFFECTS (INC. DROWSINESS).....	1	31/
H. DEPENDENCE.....	1	32/
I. ALCOHOL/DRUG INTERACTIONS.....	1	33/
J. GENERAL INFO ABOUT DRUG.....	1	34/
K. OTHER (SPECIFY) _____	1	35/

34. Some doctors like to explain things to their patients and others prefer not to explain as much. How satisfied are you with what your doctor told you about dalmane? Would you say your doctor:

told you <u>too much</u> about the drug.....	1	36/
told you <u>about the right amount</u> , or..	2	
told you <u>too little</u> ?.....	3	

35. At the time you got the prescription from your doctor, did you ask your doctor any questions about your sleeping problem or the drug?

YES.....	1	37/
NO.....	2	

36. Different doctors and pharmacists have different ideas about how drugs should be taken. I'm going to ask about several things you might have been told to be careful about. From what you were told, or what you've read or heard, do people who take dalmene have to be especially careful about (ACTION) or is it not a problem?

<u>ACTION</u>	SHOULD BE CAREFUL	NOT A PROBLEM	DON'T KNOW	
A. drinking too much water?	1	2	7	38/
B. drinking alcohol?	1	2	7	39/
C. taking other drugs?	1	2	7	40/
D. being in the sun too long?	1	2	7	41/

37. People have trouble sleeping for different reasons. Which of these reasons is closest to why you think you were having trouble sleeping? I'll read them all and you tell me which one comes closest.  
PROBE FOR ONE MAIN REASON.

(Were you) in pain due to an injury, illness,  
or recovery from surgery;..... 1 42/

(Were you) having personal worries or problems;. 2

(Were you) having to change your normal sleeping  
time due to travel or work shift  
requirements;..... 3

(Were you) in bad sleeping conditions, like in a  
noisy place;..... 4

or was it something else?..... 5

(What?) \_\_\_\_\_  
\_\_\_\_\_

38. Difficulty sleeping can mean different things for different people. When you have difficulty sleeping do you (PROBLEM) or is that not a problem for you?

<u>PROBLEM</u>	IS A PROBLEM	NOT A PROBLEM	DON'T KNOW	
A. have trouble falling asleep	1	2	7	43/
B. wake up very early in the morning (PROBE: and don't go back to sleep)	1	2	7	44/
C. wake up during the night (PROBE: but fall asleep again)	1	2	7	45/

39. INTERVIEWER CHECK Q.8 AND CIRCLE ONE:

RESPONDENT HAS TAKEN DRUG (ASK Q.40). 1 46/

RESPONDENT HAS NOT TAKEN DRUG...  
(GO TO Q.41)..... 2

40. Compared to the way you were sleeping before you got the dalmene,  
on nights you take dalmene would you say you sleep:

much better..... 1 47/

somewhat better..... 2

about the same..... 3

somewhat worse..... 4

or much worse?..... 5

SOMETIMES BETTER, SOMETIMES  
WORSE..... 6

41. Overall, how is your health now, compared to the time when you got  
the dalmene? Is it:

much better,..... 1 48/

somewhat better,..... 2

about the same,..... 3

somewhat worse,..... 4

or much worse?..... 5

SOME WAYS BETTER, SOME  
SOME WAYS WORSE..... 6

42. When you got this prescription did your doctor say there might be  
side effects from it, that side effects were not likely, or did the  
doctor not mention side effects at all?

MIGHT BE SIDE EFFECTS...(ASK Q.43).... 1 49/

SIDE EFFECTS NOT LIKELY.(GO TO Q.44).. 2

DID NOT MENTION THEM....(GO TO Q.44).. 3

43. What side effects did the doctor tell you about?

	NONE.....	000	}	
(A)	_____	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>		50-52/
(B)	_____	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>		53-55/
(C)	_____	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>		56-58/
(D)	_____	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>		59-61/
(E)	_____	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>		62-64/

44. Now I'm going to read you a list of physical problems people sometimes have. For each one, please tell me if you've had the problem or not since you got the dalmane prescription, (even though you haven't been taking it). CHECK EACH SYMPTOM IN Q.44A FIRST; IF R HAS TAKEN ANY DALMANE, FOR EACH SYMPTOM R HAD ASK Q.44B.

	44A. Have you had (any) _____ ?			44B. Do you think the _____ (is/are) due to your general condition, the dalmane, or both?					
	YES ↓ (ASK B)	NO ↓ (NEXT SYMPTOM OR Q.45)	DK ↓	NOT TAKING DRUG ↓	CONDITION ↓ NEXT SYMPTOM OR Q.45)	DALMANE ↓	BOTH ↓	DK ↓	
(1) Earaches	1	2	7	4	1	2	3	7	13-14/
(2) Bloating (feeling full of water)	1	2	7	4	1	2	3	7	15-16/
(3) Dizziness	1	2	7	4	1	2	3	7	17-18/
(4) Tenderness or bleeding of gums	1	2	7	4	1	2	3	7	19-20/
(5) Dry mouth	1	2	7	4	1	2	3	7	21-22/
(6) Excessive hair loss	1	2	7	4	1	2	3	7	23-24/
(7) Bruises you couldn't explain	1	2	7	4	1	2	3	7	25-26/
(8) Skin rash	1	2	7	4	1	2	3	7	27-28/
(9) Stomach cramps	1	2	7	4	1	2	3	7	29-30/
(10) Heartburn	1	2	7	4	1	2	3	7	31-32/
(11) Muscle spasms	1	2	7	4	1	2	3	7	33-34/
(12) Headaches	1	2	7	4	1	2	3	7	35-36/

45. INTERVIEWER, CHECK Q.44B AND CIRCLE ONE:

ANY 2's OR 3's CIRCLED...(ASK Q.46)..... 1 37/

NO 2's OR 3's CIRCLED...(GO TO Q.47B).. 2

46. If you continue to take dalmane, how likely do you think it is that you will continue to have the problems you've been having from taking dalmane? Would you say it's:

very likely,..... 1 38/

somewhat likely,..... 2

a 50-50 chance,..... 3

somewhat unlikely,..... 4

or very unlikely?..... 5

(ASK Q.47A)

47A. How much does it bother you to have these problems when you take take dalmane? Does it bother you:

47B. How much would it bother you to have some of the problems I just asked about when you take dalmane? Would it bother you:

a lot,..... 1 39/

some,..... 2

a little,..... 3

or not at all?..... 4

48. How many times in the past year have you had difficulty sleeping for more than a few days at a time? Count every time you can remember, even if you didn't take anything for it.

# OF TIMES


40-41/

FREQUENT OR CHRONIC PROBLEM.. 99

49. INTERVIEWER CHECK Q.7 AND CIRCLE ONE:

THIS IS A NEW PRESCRIPTION...(ASK Q.50)..... 1 42/

THIS IS A REFILL...(GO TO Q.51)..... 2

50. Is this the first prescription for dalmane you've ever had?

YES...(GO TO Q.52)..... 1 43/

NO....(ASK Q.51)..... 2

51. Counting all prescriptions and refills, how many dalmane prescriptions have you had in the past year?

# OF PRESCRIPTIONS

44-45/

52. Have you ever had a serious side effect or bad reaction from taking dalmane?

YES..... 1

46/

NO..... 2

53. Who first mentioned the possibility of taking dalmane (for the first prescription you had)? Was it you, was it your doctor, or was it someone else?

IF "SOMEONE ELSE": Was that person a member of your family?

CIRCLE ONE.

RESPONDENT..... 1

47/

DOCTOR..... 2

RELATIVE OF R..... 3

OTHER..... 4

DON'T RECALL..... 5

54. Have you ever used any other medicines to help you sleep such as Sleep-ese, Sominex, seconal, or chloral hydrate capsules?

YES..(ASK Q. 55)..... 1

48/

NO...(GO TO Q.57)..... 2

55. In the past year, would you say you have taken such drugs:

many times,..... 1

49/

several times,..... 2

a few times,..... 3

or not at all?..... 4

56. Have you ever had a serious side effect or bad reaction from any kind of sleeping pill besides dalmane?

YES..... 1

50/

NO..... 2



57. Do you know any friends or members of your family who are taking dalmane or have taken it in the past few years?

YES..... 1 51/

NO..... 2

58. Have you ever talked about taking dalmane with your friends or members of your family?

YES..(ASK Q.59)..... 1 52/

NO...(GO TO Q.60)..... 2

59. In general, what did they think about taking dalmane?  
(PROBE: Would you say that their feelings about dalmane were generally positive or negative?)

GENERALLY POSITIVE..... 1 53/

GENERALLY NEGATIVE..... 2

MIXED..... 3

DON'T KNOW..... 4

OTHER (SPECIFY)..... 5

60. For this prescription, did you see your doctor before you got the dalmane or was it prescribed without your doctor seeing you?

R SAW DOCTOR..... 1 54/

R DID NOT SEE DOCTOR..... 2

61. How long a period of time was there between the time you (saw/spoke with) your doctor and the time you got the prescription from the pharmacy?

A. SAME DAY.... 01

CODE "NEXT DAY" AS 02, ETC.

# DAYS

B. # WEEKS

55-56/

57-58/

62. Does the doctor who gave you this prescription usually see you at:

- a hospital,..... 1 59/
- a clinic,..... 2
- a private office,..... 3
- or someplace else?..... 4
- (Where?) \_\_\_\_\_

NEVER SAW DOCTOR AT ALL..... 8

63. Since you got this prescription from the pharmacy, have you talked to the doctor about the dalmene or your sleeping problem, either by phone or in person? IF YES: How many times?

HAVE NOT TALKED WITH DR.(GO TO Q.65). 00

OR  
TALKED # OF TIMES   60-61/  
(ASK Q.64)

64. What kinds of things did you talk with the doctor about?  
PROBE: What else?

CIRCLE ALL THAT APPLY.

- A. SAFETY OF DRUG..... 1 62/
- B. HOW TO TAKE IT, DOSAGE  
DIRECTIONS..... 1 63/
- C. REFILLS..... 1 64/
- D. SIDE EFFECTS..... 1 65/
- E. DEPENDENCE..... 1 66/
- F. ALCOHOL/DRUG INTERACTIONS..... 1 67/
- G. OTHER (SPECIFY) \_\_\_\_\_ 1 68/

65. Since you got this prescription, have you talked to the pharmacist about it or your sleeping problem, either by phone or in person?

- YES...(ASK Q.66)..... 1 69/
- NO...(GO TO Q.67)..... 2

66. What kinds of things did you talk with the pharmacist about?  
PROBE: What else?

CIRCLE ALL THAT APPLY.

- |  |   |     |
|--|---|-----|
| A. SAFETY OF DRUG.....                       | 1 | 70/ |
| B. HOW TO TAKE IT, DOSAGE<br>DIRECTIONS..... | 1 | 71/ |
| C. REFILLS.....                              | 1 | 72/ |
| D. SIDE EFFECTS.....                         | 1 | 73/ |
| E. DEPENDENCE.....                           | 1 | 74/ |
| F. ALCOHOL/DRUG INTERACTIONS.....            | 1 | 75/ |
| G. OTHER (SPECIFY) _____                     | 1 | 76/ |

CARD 04

11-12/

67. INTERVIEWER, CHECK Q.8 AND CIRCLE ONE:

- |  |   |     |
|--|---|-----|
| R HAS TAKEN DRUG (ASK Q.68).....             | 1 | 13/ |
| R HAS <u>NOT</u> TAKEN DRUG (GO TO Q.70).... | 2 |     |

68. Thinking about your own needs and the way you've used dalmane, do you think there have been any times when you should have taken it and didn't? (PROBE: Because you forgot, didn't have the pills with you, or had decided not to take them.) IF YES: How many times?

NEVER SHOULD HAVE AND DIDN'T.. 00

# TIMES  
SHOULD HAVE

--	--

14-15/

69. Have there been any times you took dalmane when you probably didn't need to? IF YES: How many times?

NO TIMES..... 00

# TIMES  
DIDN'T NEED

--	--

16-17/

CAN'T TELL/DON'T KNOW..... 77

70. (Based on your own experience), how successful do you think dalmane usually is in treating sleeping problems? Would you say it:

- |                            |   |     |
|----------------------------|---|-----|
| always works,.....         | 1 | 18/ |
| usually works,.....        | 2 |     |
| sometimes works,.....      | 3 |     |
| usually doesn't work,..... | 4 |     |
| or never works?.....       | 5 |     |

71. I'm going to read you a list of several special conditions people sometimes have. Based on whatever you've read or heard about dalmane, I'd like to know if you think there would be any special problem taking dalmane with each condition. The first is a case of poison oak. Would there be any special problem with taking dalmane for someone:

	YES	NO	DON'T KNOW	
A. who has a serious case of poison oak?	1	2	7	19/
B. who is pregnant or nursing a baby?	1	2	7	20/
C. who is taking birth control pills?	1	2	7	21/
D. who is taking medicine for epilepsy?	1	2	7	22/

72. When a person takes dalmane, is it important that they check with their doctor:

	YES	NO	DON'T KNOW	
A. if they are going to have any lab tests?	1	2	7	23/
B. if they are going to have any anesthetic for dental work or surgery?	1	2	7	24/
C. if they are going to take cough or cold medicines?	1	2	7	25/
D. if they are going to spend a week or more at high altitudes (over 6,000 feet)?	1	2	7	26/

73. From everything you know, do you think the side effects from dalmane are:

a very serious problem,.....	1	27/
a serious problem,.....	2	
a small problem, or.....	3	
no problem at all?.....	4	

74. What side effects could people get from dalmene?

NONE...(GO TO Q.77)..... 000

(A) _____	<div style="border: 1px solid black; width: 100px; height: 20px; display: flex; justify-content: space-between;"><div></div><div></div><div></div></div>	} 28-30/ 31-33/ 34-36/ 37-39/ 40-42/
(B) _____	<div style="border: 1px solid black; width: 100px; height: 20px; display: flex; justify-content: space-between;"><div></div><div></div><div></div></div>	
(C) _____	<div style="border: 1px solid black; width: 100px; height: 20px; display: flex; justify-content: space-between;"><div></div><div></div><div></div></div>	
(D) _____	<div style="border: 1px solid black; width: 100px; height: 20px; display: flex; justify-content: space-between;"><div></div><div></div><div></div></div>	
(E) _____	<div style="border: 1px solid black; width: 100px; height: 20px; display: flex; justify-content: space-between;"><div></div><div></div><div></div></div>	

75. From what you've read or heard, are some people who take dalmene more likely to get side effects than others, or does everybody have just about the same chance of getting side effects?

SOME MORE THAN OTHERS...  
(ASK Q.76)..... 1 43/

EVERYBODY HAS SAME CHANCE...  
(GO TO Q.77)..... 2

DON'T KNOW (GO TO Q.77)..... 4

76. Are (CONDITION) more likely to have a side effect?  
(PROBE: Are (CONDITION) more likely to have a side effect than people who (don't/aren't)?)

CONDITIONS	YES	NO	DON'T KNOW	
A. people with high blood pressure	1	2	7	44/
B. older people	1	2	7	45/
C. people who are allergic to penicillin	1	2	7	46/
D. people who are recovering from a serious illness	1	2	7	47/

77. If people take dalmene regularly for a long period of time, how likely is it that they will become dependent on it? Do you think it is:
- |                            |                                    |     |
|----------------------------|------------------------------------|-----|
| very likely,.....          | 1                                  | 48/ |
| DEFINE DEPENDENT IF ASKED: |                                    |     |
| It's when you get so you   | somewhat likely,.....              | 2   |
| feel like you need it and  | a 50/50 chance.....                | 3   |
| can't sleep if you don't   | somewhat <u>unlikely</u> , or..... | 4   |
| take it.                   | very <u>unlikely</u> ?.....        | 5   |
78. Now I would like to ask you a few questions about the leaflet that may have come with your prescription. Do you remember a leaflet that came with your prescription?
- |                         |   |     |
|-------------------------|---|-----|
| YES...(GO TO Q.80)..... | 1 | 49/ |
| NO...(ASK Q.79).....    | 2 |     |
79. The leaflet was white and it may have been given to you with the prescription. Do you remember getting something like this?
- |                        |   |     |
|------------------------|---|-----|
| YES...(ASK Q.80).....  | 1 | 50/ |
| NO...(GO TO Q.97)..... | 2 |     |
80. Did you read it before you started taking dalmene?
- |                              |   |     |
|------------------------------|---|-----|
| YES....(GO TO Q.82).....     | 1 | 51/ |
| NO...(ASK Q.81).....         | 2 |     |
| DON'T KNOW...(ASK Q.81)..... | 3 |     |
81. Did you get a chance to read it later?
- |                        |   |     |
|------------------------|---|-----|
| YES...(ASK Q.82).....  | 1 | 52/ |
| NO...(GO TO Q.97)..... | 2 |     |
82. After you first read it, did you ever go back and read any of it again?
- |                        |   |     |
|------------------------|---|-----|
| YES...(ASK Q.83).....  | 1 | 53/ |
| NO...(GO TO Q.84)..... | 2 |     |

83. Why did you read it again?

CIRCLE ALL THAT APPLY.

- |                                      |   |     |
|--------------------------------------|---|-----|
| A. KNEW INTERVIEWER WOULD CALL.....  | 1 | 54/ |
| B. SAFETY OF DRUG.....               | 1 | 55/ |
| C. DOSAGE DIRECTIONS.....            | 1 | 56/ |
| D. SIDE EFFECTS.....                 | 1 | 57/ |
| E. DEPENDENCE.....                   | 1 | 58/ |
| F. DRUG/FOOD/DRINK INTERACTIONS..... | 1 | 59/ |
| G. OTHER (SPECIFY) _____             | 1 | 60/ |
- 

84. Did you keep the leaflet, did you throw it away, or what?

- |                                  |   |     |
|----------------------------------|---|-----|
| KEPT IT...(ASK Q.85).....        | 1 | 61/ |
| THREW IT AWAY...(GO TO Q.88).... | 2 |     |
| GAVE IT AWAY...(GO TO Q.89)....  | 3 |     |
| OTHER (SPECIFY)...(GO TO Q.88).. | 4 |     |
- 

85. Where do you keep the leaflet? For example, is it on a shelf, in a drawer, or what?

IF "MEDICINE CHEST": Is it on the shelf or on the door?

- |                                  |   |     |
|----------------------------------|---|-----|
| ON A SHELF.....                  | 1 | 62/ |
| IN A DRAWER.....                 | 2 |     |
| ON A TABLE, DESK, COUNTER TOP... | 3 |     |
| HANGING ON WALL, DOOR.....       | 4 |     |
| OTHER _____                      | 5 |     |
- 
- |                 |   |  |
|-----------------|---|--|
| DON'T KNOW..... | 7 |  |
|-----------------|---|--|

86. What room is it in?

BATHROOM.....	1	63/
BEDROOM.....	2	
KITCHEN.....	3	
OTHER ROOM.....	4	

87. Is it usually kept with the drug or are the leaflet and the drug kept in different places?

WITH DRUG.....	1	64/
NOT WITH DRUG.....	2	

88. Did anyone else read the leaflet from your prescription?

YES...(ASK Q.89).....	1	65/
NO...(GO TO Q.90).....	2	
DON'T KNOW...(GO TO Q.90).....	3	

89. Who else read it?

CIRCLE ALL THAT APPLY.

A. SPOUSE OF R.....	1	66/
B. OTHER FAMILY MEMBER.....	1	67/
C. FRIEND.....	1	68/
D. OTHER (SPECIFY)_____	1	69/

90. Did the leaflet say anything you didn't know before you read it or was it mostly information you already had?

NEW INFORMATION.....	1	70/
MOSTLY INFORMATION ALREADY HAD.....	2	

91. In your opinion, how easy or hard to read would this leaflet be for most people? Would it be:

very easy,.....	1	71/
fairly easy,.....	2	
fairly hard, or.....	3	
very hard?.....	4	



92. About how many years of school do you think most people would need to be able to read and understand the leaflet?

NOTE: GRADE SCHOOL..... 08  
HIGH SCHOOL..... 12  
COLLEGE (B.A.,B.S.)....16  
MORE THAN COLLEGE..... 18

NUMBER  
OF YEARS     }  
DON'T KNOW.....77

72-73/

93. Did anything you read in the leaflet worry you or was most of it simply information?

WORRIED R...(ASK Q.94)..... 1

74/

DIDN'T WORRY R (GO TO Q.95).... 2

94. What part of the leaflet made you worry?

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

OFFICE USE  
A.     B.

75-78/

95. On the whole, would you say the leaflet did or did not help you to understand more about dalmane?

DID HELP..... 1

79/

DID NOT HELP..... 2

96. Would you say it did or did not help you to:

CARD 05

11-12/

- A. Follow the doctor's orders about dalmane?

DID HELP..... 1

13/

DID NOT HELP..... 2

- B. Understand the effects of dalmane?

DID HELP..... 1

14/

DID NOT HELP.....2

- C. Know when to take dalmane?

DID HELP..... 1

15/

DID NOT HELP..... 2

97. INTERVIEWER CHECK Q.8 AND CIRCLE ONE:

R HAS TAKEN DRUG...(ASK Q.98)... 1 16/

R HAS NOT TAKEN DRUG...  
(GO TO Q.106)..... 2

98. Before you started taking the dalmene, how bad was  
your sleeping problem? Would you say you were losing:

only a little sleep,..... 1 17/

a moderate amount of sleep,.... 2

a great deal of sleep, or..... 3

were you unable to sleep at  
all?..... 4

99. Before you started taking the dalmene, how much would you say your  
sleeping problem bothered you? Would you say it made you:

extremely uncomfortable,..... 1 18/

moderately uncomfortable,..... 2

slightly uncomfortable, or..... 3

not uncomfortable at all?..... 4

100. Before you started taking the dalmene, how successful did you think  
it would be in treating your sleeping problem? Did you think it  
would be:

completely successful,..... 1 19/

very successful,..... 2

somewhat successful,..... 3

or not very successful?..... 4

101. When a person has a sleeping problem like the one you had and doesn't  
take any medicine for it, how serious could it get to be? Would  
you say without any treatment it could get to be:

extremely serious,..... 1 20/

moderately serious,..... 2

somewhat serious, or..... 3

not serious at all?..... 4

102. How likely is it you will take dalmane in the future? Is it:

very likely,.....	1	21/
somewhat likely,.....	2	
a 50/50 chance,.....	3	
somewhat <u>unlikely</u> ,.....	4	
or very <u>unlikely</u> ?.....	5	

103. Do you think you will ask for a new prescription or not?

YES.....	1	22/
NO.....	2	
DON'T KNOW.....	3	

104. Overall, do you feel that any benefits you got from taking dalmane were:

less than you expected,.....	1	23/
pretty much what you expected, or.....	2	
greater than you expected?.....	3	

105. Overall, do you feel that any problems you had from taking dalmane were:

more serious than you expected,.....	1	24/
pretty much what you expected, or.....	2	
less serious than you expected?.....	3	

106. Now we're going to do something different. We are interested in what certain words mean to people. I'm going to read some words to you. I want you to listen to each word, think about what it means for a minute, and then tell me as exactly as you can what it means to you. Some of these words may be unfamiliar to you, but if you have any idea what a word means, please take a guess. Let's start with chronic. What does chronic mean to you?

RECORD RESPONSES VERBATIM. CONTINUE WITH WORDS  
B - H, SAYING EACH WORD ALOUD AND RECORDING  
RESPONSES.

- A. CHRONIC \_\_\_\_\_ ☐ 25/  
\_\_\_\_\_
- B. VACCINE \_\_\_\_\_ ☐ 26/  
\_\_\_\_\_
- C. CARCINOGEN \_\_\_\_\_ ☐ 27/  
\_\_\_\_\_
- D. PULMONARY \_\_\_\_\_ ☐ 28/  
\_\_\_\_\_
- E. GLUCOSE \_\_\_\_\_ ☐ 29/  
\_\_\_\_\_
- F. PLACEBO \_\_\_\_\_ ☐ 30/  
\_\_\_\_\_
- G. MALPRACTICE \_\_\_\_\_ ☐ 31/  
\_\_\_\_\_

Now I'd like to ask you some questions about your background. This information will help us compare the opinions of different groups of people.

107. Just so I can be sure, are you male or female?

MALE..... 1 32/

FEMALE..... 2

108. Are you married and living with your (husband/wife), widowed, divorced, separated, or have you never been married?  
"IF SINGLE ASK": Is that divorced, separated, or never married?

MARRIED AND LIVING WITH  
SPOUSE..... 1 33/

WIDOWED..... 2

DIVORCED..... 3

SEPARATED..... 4

NEVER MARRIED..... 5

SINGLE..... 6

109. INTERVIEWER CHECK Q.108 AND CIRCLE ONE:

R IS MARRIED AND LIVING WITH SPOUSE (Q.108 = 1)...  
ASK QUESTIONS ABOUT SPOUSE..... 1 34/

R HAS OTHER MARITAL STATUS (Q.108 = 2-6)...  
DO NOT ASK QUESTIONS ABOUT SPOUSE..... 2

110. How old were you on your last birthday? IF SPOUSE APPLIES: How old was your (husband/wife) on (his/her) last birthday?

A. ENTER RESPONDENT AGE

35-36/

B. ENTER SPOUSE AGE

37-38/

111. What is the highest grade or year of regular school or college you ever finished and got credit for? IF SPOUSE APPLIES: What is the highest grade or year of regular school or college your (husband/wife) finished and got credit for?

A. ENTER RESPONDENT GRADE CODE

39-40/

B. ENTER SPOUSE GRADE CODE.

41-42/

GRADE CODES	
No formal schooling.....	00
ELEMENTARY	
1st grade.....	01
2nd grade.....	02
3rd grade.....	03
4th grade.....	04
5th grade.....	05
6th grade.....	06
7th grade.....	07
8th grade.....	08
HIGH SCHOOL	
1st year (9th grade).....	09
2nd year (10th grade).....	10
3rd year (11th grade).....	11
4th year (H.S. Diploma. GED, 12th grade).....	12
COLLEGE	
1 year.....	13
2 years.....	14
3 years.....	15
4 years.....	16
POST COLLEGE	
1 year.....	17
2 years.....	18
3 years.....	19
4 years +.....	20

112. IF R OR SPOUSE COMPLETED GRADE 8 OR MORE, ASK: What is the highest diploma or degree (you have?/your husband has?/your wife has?). CIRCLE ONE CATEGORY FOR R AND SPOUSE

	A. RESPONDENT	B. SPOUSE	
NONE.....	00	00	43-46/
HIGH SCHOOL DIPLOMA.....	01	01	
ASSOCIATE, e.g., AA.....	02	02	
BA, BS.....	03	03	
MA, MS, MPA.....	04	04	
MD, LLB, PhD, JD.....	05	05	
OTHER.....	06	06	
(SPECIFY:) _____			
DOES NOT APPLY.....	NN	NN	

113. ASK Q.113-117, FIRST FOR RESPONDENT THEN FOR SPOUSE.  
 FOR RESPONDENT: What is your current employment status--are you working full-time, working part-time, in school, retired, disabled, keeping house, unemployed, or something else?  
 FOR SPOUSE: What is your (husband's/wife's) current employment status--is (he/she) working full-time, working part-time, in school, retired, disabled, keeping house, unemployed, or something else?

	A. RESPONDENT	B. SPOUSE	
WORKING FULL TIME...(GO TO Q.115).....	1	1	47-48/
WORKING PART-TIME...(GO TO Q.115).....	2	2	
IN SCHOOL...(ASK Q.114).....	3	3	
RETIRED...(GO TO Q.115).....	4	4	
DISABLED...(ASK Q.114).....	5	5	
KEEPING HOUSE...(ASK Q.114).....	6	6	
UNEMPLOYED...(ASK Q.114).....	7	7	
OTHER...(ASK Q.114).....	8	8	
(SPECIFY) _____			

114. FOR RESPONDENT: Have you ever been employed?  
 FOR SPOUSE: Has (he/she) ever been employed?

	A. RESPONDENT	B. SPOUSE	
YES...(ASK Q.115-117).....	1	1	49-50/
NO...(GO TO Q.118).....	2	2	

	A. RESPONDENT	B. SPOUSE
115. FOR RESPONDENT: What kind of business or industry (do/did) you work in--what (does/did) the place you work(ed) at make or do? FOR SPOUSE: What kind of business or industry (does/did) your (husband/wife) work in--what (does/did) the place (he/she) works(ed) at make or do?		
116. FOR RESPONDENT: What (is/was) your job title? What kind of work (are/were) you doing? FOR SPOUSE: What (is/was) (his/her) job title? What kind of work (is/was) (he/she) doing?		
117. FOR RESPONDENT: What (are/were) your most important activities or duties? FOR SPOUSE: What (are/were) (his/her) most important activities or duties?		
	(OFFICE USE) [ ] [ ] [ ] [ ] [ ] (OFFICE USE) [ ] [ ] [ ] [ ] [ ]	(OFFICE USE) [ ] [ ] [ ] [ ] [ ] (OFFICE USE) [ ] [ ] [ ] [ ] [ ]

118. What do you consider to be your own main racial or ethnic group?  
Would you say it is:

American Indian or Alaskan native..... 1 69/  
Asian or Pacific islander..... 2  
Black, but not of Hispanic origin..... 3  
Hispanic, or..... 4  
White, but not of Hispanic origin?..... 5  
OTHER..... 6

(SPECIFY: \_\_\_\_\_)

119. The next few questions are about your opinions. I'll read a statement to you and you can tell me if you agree or disagree. Here's the first statement. READ 119A. Do you agree, or disagree?

	AGREE	DISAGREE	NOT SURE	
A. I'm as healthy as most people I know.	1	3	2	70/
B. There is not much a person can do to prevent illness.	1	3	2	71/
C. When I'm sick I try to just keep going as usual.	1	3	2	72/
D. A person should take medicine only as a last resort.	1	3	2	73/
E. I always follow my doctor's instructions even if I don't understand them.	1	3	2	74/



That's the end of the interview. Now I need to get your address so I can send you the payment for being a participant.

FILL IN NAME AND ADDRESS ON CONTACT FOLDER.

You'll receive your payment in a week or so. We'll also send you a short questionnaire to fill out, if that's OK with you. It's a few more questions like the last ones I just asked. You'll get a stamped envelope to return it in and we'd appreciate your sending it back as soon as possible.

IF PPI SAY:

Before I hang up, I want to tell you that one of the reasons for the interview was to see whether the leaflets were written so that people could remember them. When I asked about side effects and reasons for not taking the drug I read you a list of several different side effects and things people should be careful about in taking the drug. Some of the things I read you were real side effects or real things to be careful about and some just sounded real, but weren't. If you have any questions about dalmane please (look at the leaflet again or) talk with your pharmacist or doctor.

IF NO PPI SAY:

Before I hang up, I want to tell you that one of the reasons for the interview was to see whether people could obtain good information about prescription drugs. When I asked about side effects and reasons for not taking the drug I read you a list of several different side effects and things to be careful about. Some of the things I read you were real side effects or real things to be careful about, and some just sounded real, but weren't. If you have any question about Dalmane please talk with your pharmacist or doctor.

Thank you very much for your help. I've enjoyed talking with you.

TIME ENDED:

--	--	--	--	--

75-78/

AM..... 1

79/

PM..... 2

Appendix D

ESTROGEN TELEPHONE SURVEY

OMB#57-S78005 Expires 12/81

VERSION 10/15/79

1-10/

CASE #

--	--	--	--	--	--	--	--	--	--	--	--	--	--

13-16/

PRESCRIPTION DRUG  
INFORMATION STUDY

TELEPHONE INTERVIEW: ESTROGEN

CARD 01

11-12/



TIME BEGAN:

--	--	--	--	--	--

17-20/

AM..... 1

21/

PM..... 2

Hello, I'm \_\_\_\_\_, calling from the Rand Corporation in Santa Monica. We're doing a study for the U.S. Department of Health, Education, and Welfare about prescription drugs. When you picked up a prescription from (NAME OF PHARMACY) you signed an authorization form that let the pharmacy give us your name to be part of this study. I'd like to do an interview with you now, over the phone, if you have time.

1. Our record from the pharmacy shows you received a prescription drug on (DATE). Do you remember the name of the drug?  
IF "MORE THAN ONE:" Tell me all the prescriptions you got that day.  
"IF HORMONE": Do you know the name of the particular hormone?

NAMES ESTROGEN OR TRADE

NAME...(GO TO Q.6)..... 1

22/

"HORMONE" ONLY (ASK Q.2)..... 2

NAMES ONLY OTHER DRUGS...

(ASK Q.2)..... 3

DOESN'T KNOW NAME...(ASK Q.2). 4

2. Did you receive a prescription for estrogen? IF "NO" OR UNSURE PROBE:  
This drug is also called (TRADE NAME).

SAID "HORMONE" IN Q.1, CONFIRMS IT

ESTROGEN...(GO TO Q.7)..... 1

23/

NOW REMEMBERS ESTROGEN...

(GO TO Q.6)..... 2

DIDN'T RECEIVE OR NOT SURE.(ASK Q.3). 3

3. This drug was in the form of pills. It cost (AMOUNT).

RECEIVED ESTROGEN...(GO TO Q.6)..... 1

24/

DIDN'T RECEIVE OR UNSURE.(ASK Q.4)... 2

CARD 01

4. This drug is a female hormone.

RECEIVED ESTROGEN..(GO TO Q.7)..... 1 25/

DIDN'T RECEIVE, OR UNSURE...  
(READ Q.5)..... 2

5. Since we're not sure you received estrogen I'd like to check our records again before we do the interview. This is not something you should worry about. Occasionally we have small mix-ups. I'll check it carefully and call you back to tell you what I find out.

TERMINATE INTERVIEW AND SEE YOUR SUPERVISOR.

6. What kind of a drug is estrogen? Would you say it's:

an anticoagulant,..... 1 26/

a female hormone,..... 2

an amphetamine,..... 3

or something else?..... 4

(SPECIFY \_\_\_\_\_)

DON'T KNOW..... 7

7. Was this prescription a new prescription or a refill?  
(PROBE: Did your doctor give you a prescription or call an order into the pharmacy for the pills you received or (DATE) or did the pharmacy already have the prescription?)

NEW PRESCRIPTION..... 1 27/

REFILL..... 2

8. Have you taken any of the pills from this prescription yet?

YES....(GO TO Q.12)..... 1 28/

NO.....(ASK Q.9)..... 2

9. What is the main reason you haven't taken any of them?  
CIRCLE ONE.

STILL USING UP PREVIOUS PRESCRIPTION...(GO TO Q.12).....	1	29/
DIDN'T NEED THEM(GO TO Q.12).....	2	
GOT DIFFERENT MEDICATION..(GO TO Q.12)	3	
FORGOT TO TAKE THEM...(GO TO Q.12)....	4	
DISCOVERED SHOULDN'T TAKE THEM... (ASK Q.10).....	5	
DIDN'T WANT TO/DOESN'T LIKE PILLS... (ASK Q.10).....	6	
FOUND OUT ABOUT BAD SIDE EFFECTS... (ASK Q.10).....	7	
READ PPI...(ASK Q.10).....	8	
OTHER...(GO TO Q.12).....	9	

10. What bothers you about this drug? (IF SIDE EFFECTS: What side effects are you worried about?)

CIRCLE ALL THAT APPLY

A. CANCER-ANY TYPE.....	1	30/
B. HEART ATTACK/ANGINA.....	1	31/
C. STROKE.....	1	32/
D. OTHER MAJOR SIDE EFFECT(S).....	1	33/
E. MINOR SIDE EFFECTS.....	1	34/
F. R's EXISTING MEDICAL CONDITIONS.....	1	35/
G. OTHER (SPECIFY).....	1	36/
H. _____	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	37-39/
I. _____	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	40-42/

11. INTERVIEWER CIRCLE ONE:

R MENTIONED LEAFLET.....	1	43/
R DID NOT MENTION LEAFLET.....	2	

12. The next set of questions is about the directions you got for taking estrogen.  
 IF R NOT TAKING DRUG: We'd like to ask them even though you're not taking it.  
 IF R OFFERS TO GET CONTAINER SAY: At this point, we'd like to know whatever you remember about the directions, without looking at them.
13. Do you always take the pills on a regular schedule, do you take them off and on when you need to, or do you take them in some other way?

REGULAR SCHEDULE...  
 (GO TO Q.17)..... 1 44/  
 ONLY WHEN NEEDED.(ASK Q.14)... 2  
 OTHER (SPECIFY)...(ASK Q.14).. 3

14. Were you told anything, personally, about how to decide when you need to begin taking estrogen by:

	YES	NO	DON'T KNOW	
A. the doctor who prescribed it?	1	2	7	45/
B. the pharmacist where you got the prescription?	1	2	7	46/

15. Over the last year, how many times did you decide you needed to begin taking estrogen?

# OF TIMES   }  
 (ASK Q.16) } 47-48/  
 THIS IS FIRST TIME...  
 (GO TO Q.17)..... 00 }

16. About how long did you take estrogen each time?  
 (PROBE: How many days or weeks or months?)

A. # OF DAYS	<input type="text"/> <input type="text"/>	49-50/
B. # OF WEEKS	<input type="text"/> <input type="text"/>	51-52/
C. # OF MONTHS	<input type="text"/> <input type="text"/>	53-54/

17. On a day when you take the estrogen, how many times a day do you take it?

ONCE..... 1 } 55/  
 OTHER NUMBER OF TIMES  }

17A. How many pills do you take each time?

ONE..... 1

OTHER NUMBER  
OF PILLS

56/

18. In a week when you take the estrogen, how many days do you take it?  
(PROBE: Do you take it every day, every other day, or what?)

EVERY DAY..... 7-7

EVERY OTHER DAY..... 1-2

TAKE 1 DAY 2 DAYS OFF..... 1-3

TAKE WEEK DAYS,  
WEEKEND OFF..... 5-7

OTHER (SPECIFY)..... -

57-58/

19. Do you take the pills every week, do you regularly skip some weeks,  
or do you sometimes skip and sometimes not skip?

EVERY WEEK...(GO TO Q.21).... 1

59/

REGULARLY SKIP...(ASK Q.20).. 2

SOMETIMES SKIP...(ASK Q.20).. 3

20. (Usually,) How many weeks do you take pills and how many weeks do  
you skip? ENTER 20A AND 20B.

SPECIFY \_\_\_\_\_

A. # WEEKS TAKE

60/

B. # WEEKS SKIP

61/

C. OTHER SCHEDULE..... 1  
(SPECIFY AT LEFT)

62/

21. INTERVIEWER, CIRCLE ONE:

RESPONDENT ANSWERED Q.13-20

FROM MEMORY..... 1

63/

RESPONDENT HAD PRESCRIPTION IN HAND.. 2

22. Were you told anything personally about how to schedule your pills by:

YES NO DON'T  
KNOW

A. the doctor who prescribed estrogen?

1 2 7 64/

B. the pharmacist where you got  
the prescription?

1 2 7 65/

23. We'd like to know how much of the estrogen from this prescription you still have. Could you find the container of pills and count how many pills you have left?

IF R WILL NOT COUNT PROBE:  
Based on how many pills  
you've taken, how many  
pills would you estimate  
are left?

A. ACTUAL COUNT  
# PILLS LEFT

(GO TO Q.24)

66-67/

ALL USED UP..(GO TO Q.27).... 00

B. ESTIMATE  
# PILLS LEFT

(ANSWER Q.23C AND ASK Q.24)

68-69/

OTHER RESPONSE...  
(ANSWER 23C AND ASK Q.24)... MM

C. REASON NO PILL COUNT ENTERED:

CAN'T FIND/KEPT AT OTHER LOCATION. 1

70/

HAVEN'T TAKEN ANY YET..... 2

REFUSED TO COUNT..... 3

OTHER (SPECIFY)..... 4

24. Do you expect to (continue to) take the estrogen from this prescription?

YES...(ASK Q.25)..... 1

71/

NO...(GO TO Q.26)..... 2

25. How long do you think it will take you to use up all the pills in this prescription?  
(PROBE: How many weeks or months?)

A. # WEEKS

72-73/

B. # MONTHS

74-75/

(GO TO Q.27)



26. Why don't you think you'll take all the pills?  
CIRCLE ALL THAT APPLY.
- A. SHORT TERM THERAPY..... 1 13/
  - B. WILL TRY TO GO OFF DRUG..... 1 14/
  - C. SIDE EFFECTS (MAJOR OR MINOR). 1 15/
  - D. PROBLEMS WITH R's MEDICAL  
CONDITIONS..... 1 16/
  - E. OTHER (SPECIFY)..... 1 17/

27. When this prescription runs out, do you think the doctor will give you a new prescription for estrogen if you want one, will want to talk about it first, will not give you a new prescription, or what?

WILL GIVE NEW PRESCRIPTION.....1 18/  
WILL TALK ABOUT IT.....2  
WON'T GIVE NEW PRESCRIPTION... 3  
OTHER (SPECIFY)..... 4

28. Did the doctor tell you anything about how long you should continue to take estrogen?

YES.....(ASK Q.29)..... 1 19/  
NO.....(GO TO Q.30)..... 2

29. What did the doctor tell you? (PROBE: Did your doctor indicate that you should take estrogen for a short time or a long time?)

SHORT TERM DRUG..... 1 20/  
LONG TERM DRUG..... 2  
OTHER (SPECIFY)..... 3

30. Did your doctor tell you anything about estrogen in general or how it works?

YES...(ASK Q.31)..... 1 21/

NO...(GO TO Q.32)..... 2

31. What did your doctor tell you? PROBE: What else?

CIRCLE ALL THAT APPLY.

A. SAFETY-POSITIVE VIEW..... 1 22/

B. SAFETY-NEGATIVE VIEW..... 1 23/

C. SAFETY GENERAL..... 1 24/

D. HOW IT WORKS, EFFECTS OF  
DRUG,..... 1 25/

E. HOW TO TAKE IT-DOSAGE  
DIRECTIONS..... 1 26/

F. REFILLS..... 1 27/

G. SIDE EFFECTS..... 1 28/

H. DURATION OF DRUG TREATMENT.... 1 29/

I. GENERAL INFO ABOUT DRUG..... 1 30/

J. OTHER (SPECIFY)..... 1 31/

---

---

32. Some doctors like to explain things to their patients and others prefer not to explain as much. How satisfied are you with what your doctor told you about estrogen? Would you say your doctor:

told you too much about drug..... 1 32/

told you about the right amount,..... 2

or told you too little?..... 3

33. At the time you got the prescription from your doctor, did you ask your doctor any questions about your illness or the drug?

YES..... 1 33/

NO..... 2

34. Did you start taking estrogen because of:

symptoms of the menopause, (GO TO Q.36A) 1

34/

because you had surgery, (ASK Q.35).... 2

or for some other reason? (ASK Q.35)... 3

What was the main reason? \_\_\_\_\_

BOTH SYMPTOMS AND SURGERY...

(GO TO Q.36A)..... 4

35. Did you have any symptoms from lack of estrogen before you started taking the pills?

YES... (ASK Q.36A)..... 1

35/

NO... (ASK Q.36B)..... 2

36A. What were all the symptoms you had when the doctor gave you this estrogen prescription? FILL IN SYMPTOMS BELOW AND ASK Q.37.

B. What were the symptoms you expected you might have? FILL IN SYMPTOMS BELOW AND GO TO Q.40.

37. IF ONE SYMPTOM CIRCLE 1 WITHOUT ASKING.  
IF MORE THAN ONE ASK:  
Which of these was the estrogen prescribed to help?

(CIRCLE "1" FOR SYMPTOMS DRUG WAS SUPPOSED TO HELP.)

A.	_____	<input type="checkbox"/>	<input type="checkbox"/>	1	36-38/
B.	_____	<input type="checkbox"/>	<input type="checkbox"/>	1	39-41/
C.	_____	<input type="checkbox"/>	<input type="checkbox"/>	1	42-44/
D.	_____	<input type="checkbox"/>	<input type="checkbox"/>	1	45-47/
E.	_____	<input type="checkbox"/>	<input type="checkbox"/>	1	48-50/
F.	_____	<input type="checkbox"/>	<input type="checkbox"/>	1	51-53/

38. INTERVIEWER, HOW MANY SYMPTOMS DID YOU CIRCLE?

ALL OF THOSE LISTED...(ASK Q.39).....	1	54/
SOME OF THOSE LISTED...(ASK Q.39).....	2	
NONE OF THOSE LISTED...(GO TO Q.40).....	3	

39. How are these symptoms now? Are the symptoms the estrogen was prescribed for:

much better,.....	1	55/
somewhat better,.....	2	
about the same,.....	3	
somewhat worse,.....	4	
or much worse?.....	5	
SOME BETTER, SOME WORSE..:.....	6	

40. Overall, how is your health now, compared to the time when you got the estrogen? Is it:

much better,.....	1	56/
somewhat better,.....	2	
about the same,.....	3	
somewhat worse,.....	4	
or much worse?.....	5	
SOME WAYS BETTER, SOME WAYS WORSE.....	6	

41. When you got this prescription did your doctor say there might be side effects from it, that side effects were not likely, or did the doctor not mention side effects at all?

MIGHT BE SIDE EFFECTS...(ASK Q.42)....	1	57/
SIDE EFFECTS NOT LIKELY.(GO TO Q.43)..	2	
DID NOT MENTION THEM....(GO TO Q.43)..	3	

42. What side effects did the doctor tell you about?

	NONE.....	000				
1.	_____	<table border="1"><tr><td></td><td></td><td></td></tr></table>				58-60/
2.	_____	<table border="1"><tr><td></td><td></td><td></td></tr></table>				61-63/
3.	_____	<table border="1"><tr><td></td><td></td><td></td></tr></table>				64-66/
4.	_____	<table border="1"><tr><td></td><td></td><td></td></tr></table>				67-69/
5.	_____	<table border="1"><tr><td></td><td></td><td></td></tr></table>				70-72/

43. Now I'm going to read you a list of physical problems people sometimes have. For each one, please tell me if you've had the problem or not since the time when you got the estrogen prescription (even though you haven't been taking it). CHECK EACH SYMPTOM IN Q43A FIRST; CIRCLE 4 AND SKIP THOSE ALREADY MENTIONED IN Q.36. IF R IS TAKING ESTROGEN ASK Q.43B FOR EACH SYMPTOM R HAD.

CARD 03

43A. Have you had any \_\_\_\_\_?

43B. Do you think the \_\_\_\_\_ (is/are) due to your general condition, the estrogen, or both?

11-12/

	IN Q.36	YES (ASK 43B OR NEXT SYMPTOM)	NO (NEXT SYMPTOM OR Q.44)	DK	CONDITION NOT TAKING DRUG	ESTROGEN (NEXT SYMPTOM OR Q.44)	BOTH	DK	
(1) Skin rash	4	1	2	7	4	1	2	3	7 13-14/
(2) Stiffness or pain in joints	4	1	2	7	4	1	2	3	7 15-16/
(3) Stomach cramps	4	1	2	7	4	1	2	3	7 17-18/
(4) Headaches	4	1	2	7	4	1	2	3	7 19-20/
(5) Dry mouth	4	1	2	7	4	1	2	3	7 21-22/
(6) Trouble falling asleep at night	4	1	2	7	4	1	2	3	7 23-24/
(7) Breast tenderness	4	1	2	7	4	1	2	3	7 25-26/
(8) Bloating (feeling full of water)	4	1	2	7	4	1	2	3	7 27-28/
(9) Vaginal bleeding or spotting	4	1	2	7	4	1	2	3	7 29-30/
(10) Soreness or bleeding of the gums	4	1	2	7	4	1	2	3	7 31-32/

44. INTERVIEWER, CHECK Q.43B AND CIRCLE ONE:

ANY 2's OR 3's CIRCLED...  
(ASK Q.45)..... 1 33/

NO 2's OR 3's CIRCLED...  
(GO TO Q.46B)..... 2

45. If you continue to take estrogen for the next six months, how likely do you think it is that you'll continue to have the problems you've had from taking estrogen? Would you say it's:

very likely,..... 1 34/  
somewhat likely,..... 2  
a 50-50 chance,..... 3  
somewhat unlikely,..... 4  
or very unlikely?..... 5  
(ASK Q.46A)

46A. How much does it bother you to have these problems when you take estrogen? Does it bother you:

46B. How much would it bother you to have some of the problems I just asked about when you take estrogen? Would it bother you:

a lot,..... 1 35/  
some,..... 2  
a little, or..... 3  
not at all?..... 4

47. Some people think there's a chance of serious health problems, like stroke, blood clots, or cancer, from taking estrogen. Others think there's not much chance of these things happening as a result of taking estrogen. How likely do you think it is that a woman would develop a serious health problem from taking estrogen if she took it for a total of six months? Is it:

very likely,..... 1 36/  
somewhat likely,..... 2  
a 50-50 chance,..... 3  
somewhat unlikely,..... 4  
or very unlikely?..... 5

48. How likely is it that she would have serious health problems if she took estrogen for a year? Is it:

very likely,.....	1	37/
somewhat likely,.....	2	
a 50-50 chance,.....	3	
somewhat <u>unlikely</u> ,.....	4	
or very <u>unlikely</u> ?.....	5	

49. What if she took estrogen for five years? Is it:

very likely,.....	1	38/
somewhat likely,.....	2	
a 50-50 chance,.....	3	
somewhat <u>unlikely</u> ,.....	4	
or very <u>unlikely</u> ?.....	5	

50. When you, yourself, think about continuing to take estrogen, how concerned are you about your chances for getting serious health problems like these? Would you say you're:

very concerned,.....	1	39/
moderately concerned,.....	2	
somewhat concerned,.....	3	
slightly concerned, or.....	4	
not at all concerned?.....	5	

51. Do you remember hearing anything about estrogen on TV or the radio?

YES.....(ASK Q.52).....	1	40/
NO.....(GO TO Q.53).....	2	

52. Did what you heard suggest that taking estrogen is a good idea, a bad idea, or was the information mixed?

GOOD IDEA.....	1	41/
BAD IDEA.....	2	
INFORMATION MIXED.....	3	
DIDN'T HEAR WHETHER GOOD OR BAD IDEA.....	4	



53. Do you remember reading anything about estrogen in the newspaper or a magazine?

YES...(ASK Q.54)..... 1 42/

NO....(GO TO. Q.55)..... 2

54. Did what you read suggest that taking estrogen was a good idea, a bad idea, or was the information mixed?

GOOD IDEA..... 1 43/

BAD IDEA..... 2

INFORMATION MIXED..... 3

DIDN'T READ WHETHER  
GOOD OR BAD IDEA..... 4

55. Have you ever taken birth control pills?

YES...(ASK Q.56)..... 1 44/

NO.....(GO TO Q. 57)..... 2

56. Altogether, how long did you take birth control pills?

A. MONTHS   45-46/

B. YEARS   47-48/

57. INTERVIEWER, CHECK Q.7 AND CIRCLE ONE:

THIS IS A NEW PRESCRIPTION...  
(ASK Q.58)..... 1 49/

THIS IS A REFILL...(GO TO Q.59)..... 2

58. (Not counting birth control pills), was this your first prescription for estrogen or have you had other prescriptions for it?

FIRST PRESCRIPTION...(GO TO  
Q.64)..... 1 50/

HAD OTHER PRESCRIPTION(S)...  
(ASK Q.59)..... 2

59. Altogether, how long has it been since you first started taking estrogen? PROBE: How many weeks, months, or years?

A. # WEEKS  51-52/  
B. # MONTHS  53-54/  
C. # YEARS  55-56/

D. HAVEN'T TAKEN IT YET..... 00

60. Before this prescription, did you ever get a leaflet giving information about estrogen with any of your old prescriptions?

YES.....(ASK Q.61)..... 1 57/  
NO.....(GO TO Q.63)..... 2  
CAN'T REMEMBER/DON'T KNOW...  
(GO TO Q.63)..... 3

61. Did you ever read the leaflet?

YES...(ASK Q.62)..... 1 58/  
NO.....(GO TO Q.63)..... 2  
CAN'T REMEMBER/DON'T KNOW...  
(GO TO Q.63)..... 3

62. About how long ago did you read the leaflet?

A. # MONTHS  59-60/  
B. # YEARS  61-62/

63. Counting all prescriptions and refills, how many prescriptions have you had for estrogen in the past year?

# PRESCRIPTIONS  63-64/

64. Who first mentioned the possibility of taking estrogen (for the first prescription you ever had)? Was it you, was it your doctor, or was it someone else? IF "SOMEONE ELSE": Was that person a member of your family?

RESPONDENT..... 1      65/  
DOCTOR..... 2  
RELATIVE OF R..... 3  
OTHER..... 4  
DON'T RECALL..... 7

65. INTERVIEWER CHECK Q.35 AND CIRCLE ONE:

R HAD SYMPTOMS BEFORE ESTROGEN  
(Q.35 = 1 OR BLANK)...(ASK Q.66).... 1      66/  
R NEVER HAD SYMPTOMS (Q.35 = 2)...  
(GO TO Q.69)..... 2

66. Before you got the first prescription for estrogen, how long were you having symptoms like the ones you're taking estrogen for? How many weeks, months, or years?

A. # WEEKS        67-68/  
B. # MONTHS        69-70/  
C. # YEARS        71-72/

67. Did you ever have those symptoms before that time, for more than a few days?

YES....(ASK Q.68)..... 1      73/  
NO.....(GO TO Q.69)..... 2

68. How many other times have you had them for more than a few days?

# TIMES        74-75/

69. Do you know any friends or members of your family who are taking estrogen or have taken it in the past few years? 11-12/

YES..... 1 13/

NO..... 2

70. Have you ever talked about taking estrogen with your friends or with members of your family?

YES....(ASK Q.71)..... 1 14/

NO.....(GO TO Q.72)..... 2

71. In general, what did they think about taking estrogen?  
(PROBE: Would you say their feelings about estrogen were generally positive or negative?)

GENERALLY POSITIVE..... 1 15/

GENERALLY NEGATIVE..... 2

MIXED..... 3

DON'T KNOW..... 4

OTHER (SPECIFY)..... 5

72. For this prescription, did you see your doctor before you got the estrogen or was it prescribed without your doctor seeing you?

R SAW DOCTOR...(ASK Q.73)..... 1 16/

R SPOKE WITH DOCTOR...(ASK Q.73)..... 2

R NEITHER SAW NOR SPOKE WITH  
DOCTOR...(GO TO Q.74)..... 3

73. How long a period of time was there between the time you (saw/spoke with) your doctor and the time you got the prescription from the pharmacy?

COUNT "NEXT DAY" AS 02, ETC.

A. SAME DAY.... 01 }

# DAYS [ ] [ ] } 17-18/

B. # WEEKS [ ] [ ] } 19-20/

74. Does the doctor who gave you this prescription usually see you at:

- a hospital,..... 1 21/
- a clinic,..... 2
- a private office,..... 3
- or someplace else?..... 4

(Where?) \_\_\_\_\_

NEVER SAW DOCTOR AT ALL..... 8

75. Since you got this prescription from the pharmacy, have you talked to the doctor about the estrogen or your symptoms either by phone or in person? IF YES: How many times?

HAVE NOT TALKED TO DR....  
(GO TO Q.77)..... 00

OR

TALKED # OF TIMES

(ASK Q.76)

22-23/

76. What kinds of things did you talk with the doctor about?

PROBE: What else?

CIRCLE ALL THAT APPLY.

- A. SAFETY OF DRUG..... 1 24/
- B. HOW IT WORKS, EFFECTS OF DRUG. 1 25/
- C. HOW TO TAKE IT, DOSAGE  
DIRECTIONS..... 1 26/
- D. REFILLS..... 1 27/
- E. SIDE EFFECTS..... 1 28/
- F. DURATION OF DRUG TREATMENT.... 1 29/
- G. GENERAL INFO ABOUT DRUG..... 1 30/
- H. OTHER (SPECIFY)..... 1 31/

77. Since you got this prescription, have you talked to the pharmacist about it or your symptoms either by phone or in person?

YES....(ASK Q.78)..... 1 32/

NO.....(GO TO Q.79)..... 2

78. What kinds of things did you talk with the pharmacist about?

PROBE: What else?

CIRCLE ALL THAT APPLY.

- |  |   |     |
|--|---|-----|
| A. SAFETY OF DRUG.....                       | 1 | 33/ |
| B. HOW IT WORKS, EFFECTS OF<br>DRUG.....     | 1 | 34/ |
| C. HOW TO TAKE IT, DOSAGE<br>DIRECTIONS..... | 1 | 35/ |
| D. REFILLS.....                              | 1 | 36/ |
| E. SIDE EFFECTS.....                         | 1 | 37/ |
| F. DURATION OF DRUG TREATMENT....            | 1 | 38/ |
| G. GENERAL INFO ABOUT DRUG.....              | 1 | 39/ |
| H. OTHER (SPECIFY).....                      | 1 | 40/ |

79. INTERVIEWER, CHECK Q.8, AND CIRCLE ONE:

R HAS TAKEN DRUG...(ASK Q.80)..... 1 41/

R HAS NOT TAKEN DRUG...  
(GO TO Q.83)..... 2

80. Now I'd like to ask a few questions about your experience with taking estrogen. Sometimes people can't take every pill right on time or they forget to take them. Were there any times in the last week when you forgot to take a pill or took it late?

YES....(ASK Q.81)..... 1 42/

NO.....(GO TO Q.83)..... 2

STOPPED TAKING DRUG...  
(GO TO Q.83)..... 3

81. How many times in the last week did you take a pill late?

# OF TIMES    
LATE 43-44/

NONE..... 00

82. How many times in the last week did you completely miss a pill?

# OF TIMES    
MISSED 45-46/

NONE..... 00

83. (Based on your own experience), how successful do you think estrogen usually is in treating the kind of problems women get from low levels of estrogen? Would you say it:

always works,.....	1	47/
usually works,.....	2	
sometimes works,.....	3	
usually doesn't work,.....	4	
or never works?.....	5	

84. The next part of the questionnaire is a series of questions about estrogen in general. You may have read or heard about some of these things or you may not have heard about them at all. For a lot of these questions there aren't really any right or wrong answers; we're just interested in what you think about these things.

85. What part of the body produces natural estrogen? Would you say it's the:

ovaries,.....	1	48/
the pituitary gland,.....	2	
or both?.....	3	
DON'T KNOW.....	7	
OTHER (SPECIFY).....	8	

86. Do you think the body slows down or stops producing natural estrogen:.

	YES	NO	DON'T KNOW	
A. when a woman is nursing a baby?	1	2	7	49/
B. at menopause or change of life?	1	2	7	50/

87. Besides being produced in the body, estrogen is also produced chemically. Have you ever heard of this kind of estrogen being used:

	YES	NO	DON'T KNOW	
A. to treat cancer in men?	1	2	7	51/
B. to prevent bone disease in older women?	1	2	7	52/
C. to prevent kidney stones?	1	2	7	53/
D. to treat diabetes?	1	2	7	54/

88. What symptoms of the menopause do you think estrogen helps?  
Does it help:

	YES	NO	DON'T KNOW	
A. hot flashes and sweating?	1	2	7	55/
(Does it help) B. feelings of sadness or depression?	1	2	7	56/
(Does it help) C. feelings of being nervous or irritable?	1	2	7	57/
(Does it help) D. vaginal discomfort?	1	2	7	58/

89. Would you say estrogen is very effective, somewhat effective, or not effective at all for:

	VERY EFFECTIVE	SOMEWHAT EFFECTIVE	NOT EFFECTIVE	DON'T KNOW	
A. helping women to feel young?	1	2	3	7	59/
B. keeping the skin soft and muscles firm?	1	2	3	7	60/

90. There are some conditions women have that doctors very often ask about before prescribing estrogen, because the conditions might get worse if a woman takes estrogen. In prescribing estrogen, do you think a doctor is especially likely to ask about or is not especially likely to ask about:

	IS LIKELY	NOT LIKELY	DON'T KNOW	
A. abnormal breast X-rays or growths on the breast?	1	2	7	61/
B. a history of heart, blood clotting, or blood pressure problems?	1	2	7	62/
C. any problems with gum disease or infections?	1	2	7	63/
D. whether there have been any problems with abnormal bleeding or spotting?	1	2	7	64/
E. any problems with arthritis or rheumatism?	1	2	7	65/
F. any problems with frequent ear infections?	1	2	7	66/



91. Once a woman is taking estrogen, is it important that she tell whoever is treating her that she takes estrogen:

	YES	NO	DON'T KNOW	
A. if she's going to have any lab tests?	1	2	7	67/
B. if she is going to spend a week or more at high altitudes (over 6,000 ft.)?	1	2	7	68/
C. if she is going to be in bed for a long time, for example because of surgery?	1	2	7	69/
D. if she's going to have any dentures or replacement teeth made?	1	2	7	70/

92. How often should a doctor examine a woman who is taking estrogen?  
Would you say:

once a year,.....	1	71/
twice a year,.....	2	
every three months, or.....	3	
every month?.....	4	

93. From everything you know, do you think the side effects or other health problems as a result of taking estrogen are:

a very serious problem,.....	1	72/
a serious problem,.....	2	
a small problem,.....	3	
or no problem at all?.....	4	

11-12/

94. In some people estrogen produces side effects that are not dangerous, but that can be uncomfortable. From what you've heard or what you know from your own experience, can you name any of these? PROBE: What others?

NONE..... 000

1. \_\_\_\_\_ ☐ ☐ ☐

13-15/

2. \_\_\_\_\_ ☐ ☐ ☐

16-18/

3. \_\_\_\_\_ ☐ ☐ ☐

19-21/

4. \_\_\_\_\_ ☐ ☐ ☐

22-24/

5. \_\_\_\_\_ ☐ ☐ ☐

25-27/

95. Some people think there are serious risks in taking estrogen. From what you've read or heard, what do you, yourself, think are the most serious risks in taking estrogen? IF "CANCER" ASK: What kind of cancer?

96. IF ONE RISK CIRCLE 1 WITHOUT ASKING. IF MORE THAN ONE ASK: Which of these is the most serious risk? CIRCLE 1 FOR THE MOST SERIOUS RISK.

NONE..... 000

A. \_\_\_\_\_ ☐ ☐

1

28-30/

B. \_\_\_\_\_ ☐ ☐

1

31-33/

C. \_\_\_\_\_ ☐ ☐

1

34-36/

D. \_\_\_\_\_ ☐ ☐

1

37-39/

E. \_\_\_\_\_ ☐ ☐

1

40-42/

F. \_\_\_\_\_ ☐ ☐

1

43-45/

97. Do you think a large dose of estrogen is more dangerous than a small dose or do you think that the amount you take doesn't matter?

LARGE DOSE MORE DANGEROUS..... 1 46/

AMOUNT DOESN'T MATTER..... 2

98. Now I would like to ask you a few questions about the leaflet that may have come with your prescription. Do you remember a leaflet that came with your prescription?

YES...(GO TO Q.100)..... 1 47/

NO...(ASK Q.99) ..... 2

99. The leaflet was white, and it may have been given to you with the prescription. Do you remember getting something like this?

YES...(ASK Q.100)..... 1 48/

NO...(GO TO Q.124)..... 2

117

100. Did you read it before you started taking estrogen?

YES....(GO TO Q.102)..... 1 49/

NO...(ASK Q.101)..... 2

DON'T KNOW...(ASK Q.101)..... 3

101. Did you get a chance to read it later?

YES...(ASK Q.102)..... 1 50/

NO...(GO TO Q.118)..... 2

117

102. After you first read it, did you ever go back and read any of it again?

YES...(ASK Q.103)..... 1 51/

NO...(GO TO Q.104)..... 2

103. Why did you read it again?  
CIRCLE ALL THAT APPLY.

A. KNEW INTERVIEWER WOULD CALL.....	1	52/
B. SAFETY OF DRUG.....	1	53/
C. DOSAGE DIRECTIONS.....	1	54/
D. SIDE EFFECTS.....	1	55/
E. HOW LONG TO TAKE.....	1	56/
F. DRUG PRECAUTIONS.....	1	57/
G. OTHER (SPECIFY).....	1	58/

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104. Did you keep the leaflet, did you throw it away, or what?

KEPT IT...(ASK Q.105).....	1	59/
THREW IT AWAY...(GO TO Q.108)..	2	
GAVE IT AWAY...(GO TO Q.109)...	3	
OTHER...(ASK Q.108) (SPECIFY)..	4	

---

105. Where do you keep the leaflet? For example, is it on a shelf,  
in a drawer, or what?

IF "MEDICINE CHEST": Is it on the shelf or on the door?

ON A SHELF.....	1	60/
IN A DRAWER.....	2	
ON A TABLE, DESK, COUNTER TOP..	3	
HANGING ON WALL, DOOR.....	4	
OTHER (SPECIFY).....	5	

---

DON'T KNOW..... 7

106. What room is it in?

BATHROOM.....	1	61/
BEDROOM.....	2	
KITCHEN.....	3	
OTHER ROOM.....	4	

107. Is it usually kept with the drug or are the leaflet and the drug kept in different places?

WITH DRUG.....	1	62/
NOT WITH DRUG.....	2	

108. Did anyone else read the leaflet from your prescription?

YES...(ASK Q.109).....	1	63/
NO...(GO TO Q.110).....	2	
DON'T KNOW...(GO TO Q.110).....	3	

109. Who else read it?  
CIRCLE ALL THAT APPLY.

A. SPOUSE OF R.....	1	64/
B. OTHER FAMILY MEMBER.....	1	65/
C. FRIEND.....	1	66/
D. OTHER (SPECIFY).....	1	67/

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110. Did the leaflet say anything you didn't know before you read it or was it mostly information you already had?

NEW INFORMATION..... 1 68/

MOSTLY INFORMATION ALREADY  
HAD..... 2

111. In your opinion, how easy or hard to read would this leaflet be for most people? Would it be:

very easy,..... 1 69/

fairly easy,..... 2

fairly hard, or..... 3

very hard?..... 4

112. About how many years of school do you think most people would need to be able to read and understand the leaflet?

NOTE: GRADE SCHOOL..... 08  
HIGH SCHOOL..... 12  
COLLEGE (B.A.,B.S.)... 16  
MORE THAN COLLEGE..... 18

NUMBER OF  
YEARS    
DON'T KNOW..... 77

70-71/

113. Did anything you read in the leaflet worry you or was most of it simply information?

WORRIED R...(ASK Q.114)..... 1 72/

DIDN'T WORRY R (GO TO Q.115)... 2

114. What part of the leaflet made you worry?

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

OFFICE USE

A.   B.    
/

73-76/

115. On the whole, would you say the leaflet did or did not help you to understand more about estrogen?

DID HELP..... 1 77/

DID NOT..... 2

116. Would you say it did or did not help you to:

11-12/

A. Follow the doctor's orders about estrogen?

DID HELP..... 1 13/

DID NOT HELP..... 2

B. Understand the effects of estrogen?

DID HELP..... 1 14/

DID NOT HELP..... 2

C. Know when to take the estrogen?

DID HELP..... 1 15/

DID NOT HELP..... 2

117. INTERVIEWER CHECK Q.8 AND Q.34-35 CIRCLE ONE

R TOOK DRUG TO CURE SYMPTOMS...(ASK Q.118)..... 1 16/

R TOOK DRUG TO PREVENT SYMPTOMS...(GO TO Q.119). 2

R HAS NOT TAKEN DRUG...(GO TO Q.124)..... 3

118. Before you started taking the estrogen, how would you describe your symptoms? Would you say they made you:

extremely uncomfortable,..... 1 17/

moderately uncomfortable,..... 2

slightly uncomfortable,..... 3

or not very uncomfortable..... 4

119. Before you started taking the estrogen, how successful did you think it would be in (treating/preventing) your symptoms? Did you think it would be:

completely successful,.....	1	18/
very successful,.....	2	
somewhat successful,.....	3	
or not very successful?.....	4	

120. When a person has symptoms like the ones you (had/might have had) and doesn't take any medicine for them, how serious could it get to be? Would you say without any treatment it could get to be:

extremely serious,.....	1	19/
moderately serious,.....	2	
somewhat serious, or.....	3	
not serious at all?.....	4	

121. When this prescription runs out, do you think you will want a new prescription, or not?

WILL WANT ONE.....	1	20/
WILL NOT WANT ONE.....	2	
DON'T KNOW.....	3	

122. Overall, do you feel that any benefits you got from taking estrogen were:

less than you expected,.....	1	21/
pretty much what you expected, or.....	2	
greater than you expected?.....	3	

123. Overall, do you feel that any problems you had from taking estrogen were:

more serious than you expected,.....	1	22/
pretty much what you expected, or.....	2	
less serious than you expected?.....	3	



124. Now we're going to do something different. We are interested in what certain words mean to people. I'm going to read some words to you. I want you to listen to each word, think about what it means for a minute, and then tell me as exactly as you can what it means to you. Some of these words may be unfamiliar to you, but if you have any idea what a word means, please take a guess. Let's start with chronic. What does the word chronic mean to you?

RECORD RESPONSES VERBATIM. CONTINUE WITH WORDS  
B - H, SAYING EACH WORD ALOUD AND RECORDING  
RESPONSES.

- A. CHRONIC \_\_\_\_\_ ☐ 23/  
\_\_\_\_\_
- B. VACCINE \_\_\_\_\_ ☐ 24/  
\_\_\_\_\_
- C. CARCINOGEN \_\_\_\_\_ ☐ 25/  
\_\_\_\_\_
- D. PULMONARY \_\_\_\_\_ ☐ 26/  
\_\_\_\_\_
- E. GLUCOSE \_\_\_\_\_ ☐ 27/  
\_\_\_\_\_
- F. PLACEBO \_\_\_\_\_ ☐ 28/  
\_\_\_\_\_
- G. MALPRACTICE \_\_\_\_\_ ☐ 29/  
\_\_\_\_\_

Now I'd like to ask you some questions about your background. This information will help us compare the opinions of different groups of people.

125. Just so I can be sure, are you male or female?

MALE.....	1	30/
FEMALE.....	2	

126. Are you married and living with your (husband/wife), widowed, divorced, separated, or have you never been married?  
IF SINGLE ASK: Is that divorced, separated, or never married?

MARRIED AND LIVING WITH SPOUSE.....	1	31/
WIDOWED.....	2	
DIVORCED.....	3	
SEPARATED.....	4	
NEVER MARRIED.....	5	
SINGLE.....	6	

127. INTERVIEWER CHECK Q.126 AND CIRCLE ONE:

R IS MARRIED AND LIVING WITH SPOUSE (Q.126 = 1)...		
<u>ASK</u> QUESTIONS ABOUT SPOUSE.....	1	32/
R HAS OTHER MARITAL STATUS (Q.126 = 2-6)...		
<u>DO NOT</u> ASK QUESTION ABOUT SPOUSE.....	2	

128. How old were you on your last birthday? IF SPOUSE APPLIES: How old was your (husband/wife) on (his/her) last birthday?

A. ENTER RESPONDENT AGE   33-34/

B. ENTER SPOUSE AGE   35-36/

129. What is the highest grade or year of regular school or college you ever finished and got credit for? IF SPOUSE APPLIES: What is the highest grade or year of regular school or college your (husband/wife) finished and got credit for?

A. ENTER RESPONDENT GRADE CODE   37-38/

B. ENTER SPOUSE GRADE CODE.   39-40/

GRADE CODES	
No formal schooling.....	00
ELEMENTARY	
1st grade.....	01
2nd grade.....	02
3rd grade.....	03
4th grade.....	04
5th grade.....	05
6th grade.....	06
7th grade.....	07
8th grade.....	08
HIGH SCHOOL	
1st year (9th grade).....	09
2nd year (10th grade).....	10
3rd year (11th grade).....	11
4th year (H.S. Diploma, GED, 12th grade).....	12
COLLEGE	
1 year.....	13
2 years.....	14
3 years.....	15
4 years.....	16
POST COLLEGE	
1 year.....	17
2 years.....	18
3 years.....	19
4 years +.....	20

130. IF R OR SPOUSE COMPLETED GRADE 8 OR MORE, ASK: What is the highest diploma or degree (you have?/your husband has?/your wife has?). CIRCLE ONE CATEGORY FOR R AND SPOUSE

	A. RESPONDENT	B. SPOUSE
NONE.....	00	00 41-44/
HIGH SCHOOL DIPLOMA.....	01	01
ASSOCIATE, e.g., AA.....	02	02
BA, BS.....	03	03
MA, MS, MPA.....	04	04
MD, LLB, PhD, JD.....	05	05
OTHER (SPECIFY).....	06	06
DOES NOT APPLY.....	NN	NN

- FOR SPOUSE: What is your (husband's/wife's) current employment status-- is (he/she) working full-time, working part-time, in school, retired, disabled, keeping house, unemployed, or something else?

132. FOR RESPONDENT: Have you ever been employed?  
FOR SPOUSE: Has (he/she) ever been employed?

133. FOR RESPONDENT: What kind of business or industry (do/did) you work in—what (does/did) the place you work(ed) at make or do?

FOR SPOUSE: What kind of business or industry (does/did) your (husband/wife) work in—what (does/did) the place (he/she) works(ed) at make or do?

134. FOR RESPONDENT: What (is/  
was) your job title? What  
kind of work (are/were)  
you doing?  
FOR SPOUSE: What (is/was)  
(his/her) job title? What  
kind of work (is/was) (he/  
she) doing?

135. FOR RESPONDENT: What (are/  
were) your most important  
activities or duties?  
FOR SPOUSE: What (are/were)  
(his/her) most important  
activities or duties?

(OFFICE USE)

--	--	--	--	--	--

(OFFICE USE)

--	--

(OFFICE USE)

--	--	--	--	--

(OFFICE USE)

--	--	--

61-66/

136. What do you consider to be your own main racial or ethnic group?  
Would you say it is:

American Indian or Alaskan native.....	1	67/
Asian or Pacific islander.....	2	
Black, but not of Hispanic origin.....	3	
Hispanic, or.....	4	
White, but not of Hispanic origin?.....	5	
OTHER (SPECIFY).....	6	

137. The last few questions are about your opinions. I'll read a statement to you and you can tell me if you agree or disagree. Here's the first statement. READ 137A. Do you agree, or disagree?

	AGREE	DISAGREE	NOT SURE	
A. I'm as healthy as most people I know.	1	3	2	68/
B. There is not much a person can do to prevent illness.	1	3	2	69/
C. When I'm sick I try to just keep going as usual.	1	3	2	70/
D. A person should take medicine only as a last resort.	1	3	2	71/
E. I always follow my doctor's instructions even if I don't understand them.	1	3	2	72/

That's the end of the interview. Now I need to get your address so I can send you the payment for being a participant.

FILL IN NAME AND ADDRESS ON CONTACT FOLDER.

You'll receive your payment in a week or so. We'll also send you a short questionnaire to fill out, if that's OK with you. It's a few more questions like the last ones I just asked. You'll get a stamped envelope to return it in and we'd appreciate your sending it back as soon as possible.

IF PPI SAY:

Before I hang up, I want to tell you that one of the reasons for the interview was to see whether the leaflets were written so that people could remember them. When I asked about side effects and reasons for not taking the drug I read you a list of several different side effects and things to be careful about. Some of the things I read you were real side effects or real things to be careful about and some just sounded real, but weren't. If you have any questions about estrogen please (look at the leaflet again or) talk with your pharmacist or doctor.

IF NO PPI SAY:

Before I hang up, I want to tell you that one of the reasons for the interview was to see whether people could obtain good information about prescription drugs. When I asked about side effects and reasons for not taking the drug I read you a list of several different side effects and things to be careful about. Some of the things I read you were real side effects or real things to be careful about, and some just sounded real, but weren't. If you have any questions about Estrogen please talk with your pharmacist or doctor.

Thank you very much for your help. I've enjoyed talking with you.

TIME ENDED

[ ] [ ] : [ ] [ ]

73-76/

AM..... 1 77/

PM..... 2

Appendix E

MAIL QUESTIONNAIRE

The mail questionnaires for all three drugs were exactly the same except for the name of the drug.

OMB# 57-S78005 Expires 12/81



ID NUMBER

1-4/

5/1

6-14/

**PRESCRIPTION DRUG INFORMATION STUDY**

**ERYTHROMYCIN**

We are interested in your opinions about prescription drugs, medical care, and your health. Please answer all the questions. If you would like to comment on any questions, please do so in the left margin. Your comments will be read and taken into account.

The same person who answered the telephone interview should fill out this questionnaire. Please send it back as soon as you can. Use the prepaid return envelope or send it to:

Prescription Drug Information Study  
The Rand Corporation  
1700 Main Street  
Santa Monica, CA. 90406      Thank you!

**PART ONE - PRESCRIPTION DRUGS**

1. Where do you usually have your prescriptions filled?  
(MARK ONE ANSWER BOX.)

- ☐ MAINLY AT ONE PHARMACY  
☐ AT TWO OR THREE DIFFERENT PHARMACIES  
☐ NO SPECIAL PHARMACY - WHEREVER CONVENIENT

15/

2. What is first, second, and third most important in deciding where to have prescriptions filled?

(PUT APPROPRIATE NUMBER IN EACH BOX.)

- |  |  |     |
|--|--|-----|
| <input type="checkbox"/> MOST IMPORTANT        | 1 CONVENIENT LOCATION OF PHARMACY                | 16/ |
|  | 2 CAN USE CHARGE CARDS OR ACCOUNT                |     |
|  | 3 LIKE OR TRUST PHARMACIST                       |     |
| <input type="checkbox"/> SECOND MOST IMPORTANT | 4 LOW PRICES FOR PRESCRIPTIONS                   | 17/ |
|  | 5 PROVIDES GOOD INFORMATION ABOUT DRUGS          |     |
|  | 6 MAINTAINS RECORD OF MY PRESCRIPTIONS           | 18/ |
| <input type="checkbox"/> THIRD MOST IMPORTANT  | 7 DELIVERS PRESCRIPTIONS TO MY HOME              |     |
|  | 8 CONVENIENT PLACE TO BUY NON-PRESCRIPTION ITEMS |     |

3. About how many times have you had a prescription filled during the last 12 months?  
(MARK ONE ANSWER BOX.)

- ☐ ONE OR TWO TIMES  
☐ THREE TO FIVE TIMES  
☐ SIX TO TEN TIMES  
☐ MORE THAN TEN TIMES

19/



## PART TWO - HEALTH CARE AND DOCTORS

Here are some things people sometimes say about health care and doctors. Please circle one of the numbers on each line to show how much you agree or disagree with each statement. (For example, if you strongly agree with a statement, circle a 1. If you disagree, circle a 4, etc.) Some of the statements sound alike, but none is repeated.

CIRCLE <u>ONLY ONE</u> NUMBER FOR EACH STATEMENT.	Strongly		Not		Strongly	
	Agree	Agree	Sure	Disagree	Disagree	
1. Anyone can learn a few basic health rules which can go a long way in preventing illness.	1	2	3	4	5	20/
2. Most doctors carefully explain what will happen to their patients.	1	2	3	4	5	21/
3. I always follow my doctors instructions even if I don't really understand them.	1	2	3	4	5	22/
4. When a treatment involves risks, doctors always discuss those risks with the patient.	1	2	3	4	5	23/
5. Prescription drugs frequently do more harm than good.	1	2	3	4	5	24/
6. A person should take medicine only as a last resort.	1	2	3	4	5	25/
7. Many diseases are not as serious as people say they are.	1	2	3	4	5	26/
8. Good doctors nearly always agree on how to treat a specific illness.	1	2	3	4	5	27/
9. When I trust my doctor I don't care about having everything explained to me.	1	2	3	4	5	28/
10. Doctors are very careful to check everything when examining their patients.	1	2	3	4	5	29/
11. It mainly takes good medical care to get over an illness.	1	2	3	4	5	30/
12. Prescription drugs are almost always helpful.	1	2	3	4	5	31/

Please continue on next page.

	Strongly Agree	Agree	Not Sure	Disagree	Strongly Disagree	
13. Doctors don't always explain to their patients the risks involved in certain treatments.	1	2	3	4	5	32/
14. Good health is largely a matter of luck.	1	2	3	4	5	33/
15. Most doctors explain things clearly so the patient can understand them.	1	2	3	4	5	34/
16. When I have a medical problem, I want to know all about it.	1	2	3	4	5	35/
17. Its better to take a sleeping pill than to miss a night of sleep.	1	2	3	4	5	36/
18. Medical care can't do much for you if you're really sick.	1	2	3	4	5	37/
19. I don't like to do what the doctor tells me unless I understand the reason.	1	2	3	4	5	38/
20. Taking care of yourself won't affect whether you get sick or not.	1	2	3	4	5	39/
21. Doctors don't usually explain your medical problem to you.	1	2	3	4	5	40/
22. I'd rather my doctor just told me what to do.	1	2	3	4	5	41/
23. Doctors relieve or cure only a few of the medical problems their patients have.	1	2	3	4	5	42/
24. Drugs are always prescribed for good reason.	1	2	3	4	5	43/
25. When it comes to health there is no such thing as bad luck.	1	2	3	4	5	44/
26. When there is an important medical decision to make regarding my treatment, I want to be given enough information so that I can help make that decision.	1	2	3	4	5	45/
27. There is little a person can do to prevent illness.	1	2	3	4	5	46/
28. Doctors don't always check everything they should check when examining their patients.	1	2	3	4	5	47/

Please continue on next page.

-4-

	Strongly Agree	Agree	Not Sure	Disagree	Strongly Disagree	
29. Even good doctors disagree about how to treat an illness.	1	2	3	4	5	48/
30. Its always silly to suffer if a medicine will make you feel better.	1	2	3	4	5	49/
31. I think my doctor knows best, so I don't ask many questions.	1	2	3	4	5	50/
32. Doctors seldom explain why they order lab tests and x-rays.	1	2	3	4	5	51/
33. Some kinds of illnesses are so bad that nothing can be done about them.	1	2	3	4	5	52/
34. Doctors never expose their patients to unnecessary risk.	1	2	3	4	5	53/
35. In the long run, people who take good care of themselves stay healthier and get well more quickly.	1	2	3	4	5	54/
36. Sometimes doctors prescribe medicine without explaining what it is for.	1	2	3	4	5	55/
37. Taking prescription drugs always involves some risk.	1	2	3	4	5	56/
38. Most people are helped a great deal when they go to a doctor.	1	2	3	4	5	57/
39. Taking a tranquilizer is hardly ever a good idea.	1	2	3	4	5	58/
40. I much prefer doctors who explain things to me over those who do not.	1	2	3	4	5	59/
41. Sometimes doctors prescribe treatments that involve unnecessary risks.	1	2	3	4	5	60/
42. Most doctors take time to explain things to their patients.	1	2	3	4	5	61/

Please continue with Part Three on the next page.

**PART THREE - YOUR HEALTH**

- o These questions are about how you feel about your health.
- o For each pair of statements below, please circle the number that shows whether the statement on the right or the statement on the left describes you best. (For example, if the statement on the left describes you best, circle a 1. If the statement on the right describes you best, circle a 5. If your feeling is in between, circle a number between 1 and 5.) Please circle only one number for each pair of statements.

o How do you feel about your health?      **CIRCLE ONLY ONE NUMBER FOR EACH PAIR OF STATEMENTS.**

- |   |   |   |         |   |   |   |     |
|---|---|---|---------|---|---|---|-----|
| 1. I'm much healthier than most people I know.      | 1 | 2 | 3       | 4 | 5 | I'm much less healthy than most people I know.                  | 62/ |
|   |   |   | Neither |   |   |   |     |
| 2. I have often been seriously ill.                 | 1 | 2 | 3       | 4 | 5 | I have never been seriously ill.                                | 63/ |
|   |   |   | Neither |   |   |   |     |
| 3. In the future I will probably be very healthy.   | 1 | 2 | 3       | 4 | 5 | In the future I will probably be sick a lot.                    | 64/ |
|   |   |   | Neither |   |   |   |     |
| 4. I often worry about my health.                   | 1 | 2 | 3       | 4 | 5 | I seldom worry about my health.                                 | 65/ |
|   |   |   | Neither |   |   |   |     |
| 5. When I'm sick I try to just keep going as usual. | 1 | 2 | 3       | 4 | 5 | When I'm sick the best thing seems to be to just give in to it. | 66/ |
|   |   |   | Neither |   |   |   |     |
| 6. My body seems to resist illness very well        | 1 | 2 | 3       | 4 | 5 | When there is something going around, I usually catch it.       | 67/ |
|   |   |   | Neither |   |   |   |     |
| 7. My health is excellent                           | 1 | 2 | 3       | 4 | 5 | My health is very poor.   | 68/ |
|   |   |   | Neither |   |   |   |     |

Please continue with Part Four on the next page.

**PART FOUR - TAKING ERYTHROMYCIN**

- o These questions are about how you feel about taking erythromycin.
- o For each pair of words below, please circle the number that comes closest to how you feel about taking erythromycin. ( For example, if you feel that taking erythromycin is unpleasant circle a 1 for the first statement. If you think it's pleasant, circle a 7. If you feel it's in between, circle a number between 1 and 7.) Circle only one number for each pair of words.

- o For me, taking erythromycin is: CIRCLE ONLY ONE NUMBER FOR EACH PAIR OF STATEMENTS.

1. Unpleasant	1	2	3	4	5	6	7	Pleasant	69/
				Neither					
2. Foolish	1	2	3	4	5	6	7	Wise	70/
				Neither					
3. Safe	1	2	3	4	5	6	7	Risky	71/
				Neither					
4. Harmful	1	2	3	4	5	6	7	Beneficial	72/
				Neither					
5. Useful	1	2	3	4	5	6	7	Useless	73/
				Neither					
6. Bad for me	1	2	3	4	5	6	7	Good for me	74/
				Neither					
7. Valuable	1	2	3	4	5	6	7	Worthless	75/
				Neither					
8. Ineffective	1	2	3	4	5	6	7	Effective	76/
				Neither					
9. Responsible	1	2	3	4	5	6	7	Irresponsible	77/
				Neither					

Please continue with Part Five on next page.

**PART FIVE - ANYTHING ELSE?**

Is there anything else you would like to tell us about your experience with this drug or the information you received about it? If so, please use this space. Any comments you make will be helpful.

78-79/

Thank you for helping with this study. If you would like a summary of the results, please check the box below and we'll see that you receive one.

☐ YES, I would like a copy of the results.

8/

(A complete analysis of the results will be ready in eight months to a year. We will mail it to you as soon as possible.)

Appendix F

VALIDATION QUESTIONNAIRE

PRESCRIPTION DRUG  
INFORMATION STUDY

-248-

1-10.

TELEPHONE INTERVIEW  
VALIDATION FORM

CASE #

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11-14

Hello. May I speak to (NAME OF RESPONDENT)? I'm \_\_\_\_\_, from The Rand Corporation, working on the Prescription Drug Information Study. As a routine part of the study, we check back with a percentage of the people we interview to be sure the survey was done accurately. This will only take a few minutes.

1. Did an interviewer for the Prescription Drug Information Study interview you, by telephone, about your (DRUG) prescription on:

MONDAY	<input type="checkbox"/>	THURSDAY	<input type="checkbox"/>	SUNDAY	<input type="checkbox"/>	YES...(GO TO Q.3)... 1 15/
TUESDAY	<input type="checkbox"/>	FRIDAY	<input type="checkbox"/>			NO...(ASK Q.2)..... 2
WEDNESDAY	<input type="checkbox"/>	SATURDAY	<input type="checkbox"/>			

DATE \_\_\_\_\_

2. Have you been interviewed recently for this study? (PROBE: Has anyone in your household been interviewed?)

YES...(ASK 2A)..... 1 16/  
NO...(READ 2B)..... 2

- 2A. IF YES: When did the interview take place?

DAY OF WEEK: \_\_\_\_\_ DATE: \_\_\_\_\_ / \_\_\_\_\_  
MONTH DAY

- 2B. IF NO: Thank you for your help, but there seems to be a problem with the information I have. I'll check our records again and may be calling you back. END OF VALIDATION.

3. About how long did the interview take?

PROBLEM IF INTERVIEW TOOK  
LESS THAN 20 MINUTES.

A. HOURS

--	--

17-18/

B. MINUTES

--	--

19-20/

4. Based on the information you got about the study at the pharmacy where you picked up your prescription for (DRUG), were you expecting the interviewer to call or was it not something you expected?

EXPECTED INTERVIEW.... 1 21/  
KNEW, HAD FORGOTTEN... 2  
NOT EXPECTED..... 3

5. Did you receive a leaflet about (DRUG) at the time you got your prescription from the pharmacy?

YES...(ASK Q.6)..... 1 22/  
NO...(GO TO Q.8)..... 2



6. Do you still have it around?

YES...(ASK Q.7)..... 1 23/

NO...(GO TO Q.8)..... 2

7. Would you mind looking at the leaflet and telling me the number in the upper right hand corner?

A. PPI NUMBER  -  -  24-26/

B. CAN'T FIND..... 1 27/

REFUSED..... 2

OTHER..... 3

SPECIFY: \_\_\_\_\_

8. Are there any comments you would like to make about the study in general, the interview, or the interviewer? RECORD VERBATIM AND CODE.

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A. NO COMMENT..... 1 28/

B. STUDY COMMENT..... 1 29/

C. INTERVIEW COMMENT..... 1 30/

D. INTERVIEWER COMMENT..... 1 31/

E. POST-FIELD COMMENT..... 1 32/

F. OTHER..... 1 33/

Thank you very much for your help.

9. CODE RESULT OF VALIDATION:

CLEAN...(END)..... 1 34/

PROBLEM...(EXPLAIN)..... 2

REFUSED TO VALIDATE...(EXPLAIN)..... 3

COULD NOT BE REACHED...(END)..... 4

EXPLAIN: \_\_\_\_\_

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Appendix G

PARTS 1 AND 2 OF THE CONSUMER SURVEY

The Consumer Survey for all three drugs were exactly the same except for the name of the drug.

PRESCRIPTION DRUG  
INFORMATION STUDY

CONSUMER SURVEY: ESTROGEN



(CARD 01)		1-10/ 11-12/ 13-15/ 16-18/ 19-23/
PPI#	S - - -	
GROUP ID	- - -	
	- - - - -	
OFFICE USE ONLY		

DIRECTIONS:

- Please try to answer every question. If you are not sure about an answer, choose the one that seems closest to what you think.
- Record your answer by circling a number, writing a number in the box, or writing an answer on the line, as indicated. Please print clearly.
- If you have any questions raise your hand and someone will come to you.

PART ONE - DESCRIBING THE LEAFLET

How would you describe the leaflet you just read? For each pair of words below, please circle the number that shows your opinion. For example, in the first pair of words, if you would describe the leaflet as thick you would circle a number 1. If you would describe it as thin, you would circle a 7. If you would describe it as in

circle a number for each pair of words

(5) Attractive	1	2	3	4 Neither	5	6	7	Unattractive	28/
(6) Opinionated	1	2	3	4 Neither	5	6	7	Factual	29/
(7) Dull	1	2	3	4 Neither	5	6	7	Interesting	30/
(8) Detailed	1	2	3	4 Neither	5	6	7	Vague	31/
(9) Balanced	1	2	3	4 Neither	5	6	7	One-sided	32/
(10) Alarming	1	2	3	4 Neither	5	6	7	Reassuring	33/
(11) Thorough	1	2	3	4 Neither	5	6	7	Sketchy	34/
(12) Wordy	1	2	3	4 Neither	5	6	7	To the point	35/
(13) Good	1	2	3	4 Neither	5	6	7	Bad	36/
(14) Childish	1	2	3	4 Neither	5	6	7	Adult	37/
(15) Clear	1	2	3	4 Neither	5	6	7	Unclear	38/
(16) Hard to remember	1	2	3	4 Neither	5	6	7	Easy to remember	39/

PLEASE CONTINUE WITH PART TWO.

# PART TWO - REASONS FOR PROVIDING THE LEAFLET

This is a list of possible reasons for providing a leaflet like the one you just read to women who take estrogen. For each possible reason, circle the number that shows whether you think it is or is not a reason. For example, if you definitely think it is a reason, circle a 1. If it probably is not a reason, circle a 4, etc.

	Definitely A Reason	Probably A Reason	Not Sure	Probably Not A Reason	Definitely Not A Reason	
1. Tell people how to take the drug properly.	1	2	3	4	5	40/
2. Help people to know when they need to call the doctor.	1	2	3	4	5	41/
3. Allow people to decide whether or not to take the drug.	1	2	3	4	5	42/
4. Teach people to recognize side effects.	1	2	3	4	5	43/
5. Help people follow their doctor's orders.	1	2	3	4	5	44/
6. Warn people who shouldn't take the drug.	1	2	3	4	5	45/
7. Save the doctor's time explaining things to people.	1	2	3	4	5	46/
8. Get people to take more responsibility for their health.	1	2	3	4	5	47/
9. Tell people what to do if they get a side effect.	1	2	3	4	5	48/
10. Help people take the right amount of the drug.	1	2	3	4	5	49/
11. Tell people to avoid things that are dangerous when taking the drug.	1	2	3	4	5	50/
12. Give people the facts about the drug.	1	2	3	4	5	51/
13. Help drug companies avoid lawsuits.	1	2	3	4	5	52/

	Definitely A Reason	Probably A Reason	Not Sure	Probably Not A Reason	Definitely Not A Reason	
14. Make people decide for themselves whether or not they should take the drug.	1	2	3	4	5	53/
15. Make people more cooperative with their doctors.	1	2	3	4	5	54/
16. Help people to ask their doctors better questions.	1	2	3	4	5	55/
17. Help doctors avoid lawsuits.	1	2	3	4	5	56/
18. Help pharmacists to give better service.	1	2	3	4	5	57/
19. Help people understand how the drug works.	1	2	3	4	5	58/
20. Help doctors to give better care.	1	2	3	4	5	59/
21. Help people understand how treatments work.	1	2	3	4	5	60.

PLEASE CONTINUE WITH PART THREE.



DESIGN OF THE PRESCRIPTION DRUG INFORMATION STUDY