1984 Drug Information for the Health Care Provider

USP DI™

Vol I

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Vol. I

By authority of the United States Pharmacopeial Convention, Inc.

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Foreword

THE NATIONAL CONSENSUS

This 2-volume set is the national consensus on the clinically relevant drug use information needed by the patient and needed by those practitioners caring for the patient who is taking the medicine.

The national consensus. A proud claim. It is based on the comprehensiveness of the involvement of all interested parties, the unbiased structure of the system, and the constant public access to the system.

- The most elaborate and complete expert advisory panel system ever created in the health field; a cross-fertilized matrix of:

  —drug-specific panels, looking at the drug use information from the standpoint of its scientific accuracy in each of the therapeutic or medical specialty areas;

  —practice oriented panels, looking at the drug use information from the standpoint of its utility in each of the professions that care for patients who use the drug;

  —and a panel of consumers who watch over language, format, and general approach.

- The most elaborate and complete system to secure an unbiased consensus; or, more properly, to secure a balance of biases, since no human or human endeavor is ever unbiased:

  —the panelists, all volunteers, are chosen by the USP Committee of Revision member who represents that particular area or specialty;

  —the USP Committee of Revision members are elected for their individual expertise, regardless of their current place of employment or organizational memberships;

  —and the electors in this nation-wide election procedure are delegates of each college and state association in medicine and pharmacy, 22 national scientific, professional and trade associations, and eight agencies of the federal government that are concerned with drugs.

- The most elaborate and complete system for public review of the text that is proposed by the Panels for adoption by the Committee of Revision:

  —several hundred reviewers are designated by colleges, associations, and government agencies;

  —researchers and manufacturers involved with the individual drug provide review;

  —anyone in the world can subscribe to *USP DI Review*, the bimonthly publication in which proposed additions and deletions are published, and send in their comments and suggestions;

  —and annual publication of *USP DI* and bimonthly supplements provide for continuous review and updating.

The national consensus. Why is such an elaborate and costly system needed? Because patients need consistency and reinforcement in the information given to them; because the professions and the public need confidence in the information they give and get; and because the provision of patient information about prescription drugs breaks and bends a number of established legal boundaries.

- Consistency and reinforcement are accepted principles of education. It is important, therefore, that the patient receive essentially the same information from both the prescriber and the dispenser.

- Confidence by the professions is exemplified in the use of *USP DI* by the American Medical Association for its *Patient Medication Instruction (PMI)* sheets, by the National Association of Retail Druggists for its *Patient Information Leaflets (PILs)*, and by the Canadian Pharmaceutical Association for its *Supplementary Information on Medications (SIM)*, as well as by numerous state pharmacy associations and practice sites.

• The over-confidence in medicinemen and quacks by one segment of the public, the historic distrust of big business and of government by other segments, and the general high standing of pharmacists and physicians in the public esteem dictate a patient information system based in the health professions in order to have the public's continuing confidence.

• Legal barriers and legal threats based on decades of non-information are shifting before the increasing demand for public drug use information:

—pharmacists, who in some states were prohibited from discussing a prescription drug with the patient, are now legally required to give patient information for certain drugs and are proclaimed by leaders in pharmacy as the source of patient information on any drug;

—physicians, who have been the gate-keepers of information to patients about prescription drugs, are being urged by leaders in medicine to open the gates wider;

—and drug manufacturers, who have fulfilled their legal obligation by providing information only to the prescriber (the government generally did not allow them to do more), are now being urged by the government to voluntarily provide information to patients—in some instances some manufacturers sense that commercial advantages may be obtained.

The shifting of legal barriers and requirements should be less litigious by having this strong national consensus on what is the generally appropriate content of patient information in 1984. Of course, this works both ways. The practitioner who bases his or her information on the national consensus and then individualizes to the patient should have a better defense. The practitioner who ignores it, or who continues the tradition of providing no information, is at greater legal risk.

William M. Heller
Executive Director, USPC

Rockville, Maryland
November 1, 1983

Preface

Since 1820, the United States Pharmacopeia has set standards for the medications used by the American public. In establishing the Pharmacopeia, the founders were reacting to an unmet need of the professions and their patients—that is, the need for generally accepted procedures for the preparation of medications which would allow for confidence in their use.

The need for quality standards remains and the work of USP in establishing those standards continues. However, additional needs regarding the use of medications have arisen, within both the health care provider and health care recipient populations. Some of these newly recognized needs relate to information sources. *USP DI* is one reaction to, and a start at fulfilling at least a portion of, these previously unmet needs.

Responding to a resolution adopted at the 1970 meeting of the Pharmacopeial Convention to increase in the Pharmacopeia or in a companion volume the amount of information that would be useful to pharmacists and others, the 1970-1975 Subcommittee on Posology and Related Information, under the chairmanship of John A. Owen, Jr., M.D., expanded the category and dose information and introduced in the USP XIX monographs of many dosage forms a section entitled Dispensing Information. This information served as a basic reminder or general guide to the pharmacist, who could vary or omit it in accordance with the best interests of the patient or particular circumstances involved.

Continuing this development, the 1975-1980 Subcommittee, under the chairmanship of Harry C. Shirkey, R.Ph., M.D., greatly expanded the amount of information, focusing on that believed useful in attempting to enhance the safe and effective use of a medication once it was prescribed. This included information relating to dispensing, administration, monitoring, and/or patient consultation. The work of the Subcommittee resulted in the first edition (1980) of *USP DI*.

USP DI is, and it always will be, a work in progress. The information is under constant revision. The 1984 edition incorporates the experiences and comments generated by previous editions. The text has been reviewed for changes and revised accordingly.

USP DI is an annual publication. Each edition is supplemented by publication of an update every two months. *USP DI Update* presents monographs on selected, newly marketed drugs as well as significant changes in the information base of previously marketed drugs. Not all new drugs and not all new information on drugs already in *USP DI* will appear in *USP DI Update*. Updates, therefore, are only an interim supplement to the current annual *USP DI* and are insufficient to keep subsequent editions up-to-date.

Development of USP DI

The information in *USP DI* is the result of a nation-wide consensus-generating system (with world-wide input).

Using the parameters established by the USP Drug Information Division Executive Committee of Revision (previously the USP Subcommittee on Posology and Related Information), staff develops draft monographs for each agent selected for inclusion in *USP DI*. These drafts are reviewed by the appropriate Advisory Panel(s) and other designated reviewers and are revised accordingly. Revised monographs are then published in *USP DI Review* for general public review and comment.

The comments generated by a draft's publication in *USP DI Review* are fed back into the USP Advisory Panel system. If substantive changes result, the monograph is again published in *USP DI Review* showing the proposed changes, publication deadlines permitting. The process is repeated as required to develop consensus.

Of course, the consensus can change from one edition to the next and users of *USP DI* are encouraged to submit comments at any time to:

USP
Drug Information Division
12601 Twinbrook Parkway
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Organization of USP DI

USP DI comprises two distinct sections. The first volume includes the DI monographs arranged in alphabetic order. The index includes established names, categories of use, selected medical information such as pregnancy warnings and breast-feeding warnings, cross-references by brand names (both U.S. and Canadian), and older nonproprietary names. The second volume, *Advice for the Patient,* includes the lay language versions of the patient consultation guidelines found in Volume I. These lay language versions are intended to be used at the discretion of the provider as an aid to patient consultation if written information would be of benefit or if it is requested by the prescriber. Brand and generic names are cross-referenced in the index of *Advice for the Patient.*

The individual DI Volume I monograph covers the basic information which is applicable to that substance when used for a specific effect (e.g., Systemic). Information which is unique for a specific dosage form of that base substance is then included under that specific dosage form heading. To illustrate this system, assume that DRUG X is used for its systemic and its topical effects. Also assume that the drug is available in the following dosage forms: cream, injection, ointment, syrup, and tablet. The *USP DI* Volume I monograph for DRUG X would be organized as follows:

DRUG X (Systemic)
[General information applicable to Drug X's systemic use.]
Drug X Syrup
Drug X Tablets
Drug X Injection
[Specific information applicable to each of the systemic dosage forms.]
DRUG X (Topical)
[General information applicable to Drug X's topical use.]
Drug X Cream
Drug X Ointment
[Specific information applicable to each of the topical dosage forms.]

Where appropriate, other major headings based on specific effect are made for Dental, Inhalation-Local, Nasal-Local, Ophthalmic, Oral-Local, Otic, Parenteral-Local, Rectal-Local, or Vaginal use.

Whenever feasible, monographs are grouped under family headings. This permits a sizable saving of space and also allows the practitioner to readily identify differences among agents of the same family. Significant differences are addressed in charts and in Summary of Differences sections.

Where appropriate, the following headings and subheadings are employed in organizing the information for each DI Volume I monograph:

- Category
  - Indications
- Pharmacology
  - Mechanism of action
  - Other actions
  - Absorption
  - Distribution
  - Protein binding
  - Metabolism
  - Half-life
  - Onset of action
  - Time to peak concentration
  - Peak serum concentration
  - Time to peak effect
  - Duration of action
  - Excretion
    - In dialysis
- Precautions to Consider
  - Cross-sensitivity
  - Carcinogenicity
  - Tumorigenicity
  - Mutagenicity
  - Pregnancy
  - Breast-feeding
  - Pediatrics
  - Geriatrics
  - Drug interactions and/or related problems
  - Diagnostic interference
    - With diagnostic test results
    - With physiology
  - Medical problems
  - Patient check-ups
- Side/Adverse Effects
  - Those indicating need for medical attention
  - Signs of overdose
  - Those indicating need for medical attention only if they continue or are bothersome
- Patient Consultation
  - Before using this medication
  - Proper use of this medication
  - Precautions while using this medication
  - Side/adverse effects
- General Dosing Information
  - For treatment of overdose
- Dosage forms (each separate)
  - Usual adult dose
  - Usual adult prescribing limits
  - Usual pediatric dose
  - Strengths usually available
  - Packaging and storage
  - Preparation of dosage form
  - Stability
  - Incompatibilities
  - Label
  - Additional information

Description and Limitations of Information Included

The basic premise on which *USP DI* has been built is that certain sets of information (which we characterize as dispensing information) are applicable to the postprescription writing period, just as certain sets of information are applicable to the pre-prescription-writing period (prescribing information). Prescribing information is basically "full disclosure" information and is needed by the prescriber in order to make the decision as to whether a specific patient should be given a specific medication. Dispensing information, on the other hand, is written under the assumption that the decision to prescribe has already been made. *USP DI* is not intended to be "full disclosure" information.

USP DI contains selected information. Selection is based on what is considered by the Committee of Revision and its Advisory Panels to be practical, clinically significant information needed to assist in the monitoring of drug use and to help assure that a drug is being safely and effectively used. It is meant to aid the health care professional and the patient in minimizing the risks and enhancing the benefits of drug use. Ultimately, the information required is defined by the practice standards of medicine, pharmacy, nursing, dentistry, and the other health professions as well as by the information needs of the patient.

Readers are advised that the information may contain statements that differ from those in the "full disclosure" information labeling approved or required by the United States or Canadian governments.

Selected brand names are included in the monographs as well as in the indexes of both volumes for ease of reference purposes only. The inclusion of a brand name is not intended as an endorsement of a particular product. The omission of a particular brand name does not indicate that the article was judged to be inferior or inadequate. The inclusion of various brands bears no relationship to and is not intended to affect any applicable brand interchange requirements.

Category/Indications—Statements of categories of use and indications are provided for each article as useful information.

The category of use indicates the area of therapeutic utility for which the drug was included and generally represents an application of the best known pharmacologic action of the article or its active ingredient. The statement is not intended to be all inclusive nor to indicate that the article may have no other activity or utility.

Indications of use stated in manufacturers' labeling and approved by the U.S. Food and Drug Administration are generally included, as well as additional unlabeled indications selected by USP Advisory Panels.

New uses for approved products that are not reflected in a product's labeling are often discovered after marketing. Before a pharmaceutical manufacturer may include any new indications in the labeling for a particular drug (and to promote the product for those uses), it must obtain the Food and Drug Administration's approval for the uses. Such approval requires the completion of adequate and well-controlled clinical trials to document the drug's safety and efficacy for the new uses. Since clinical trials may take considerable time and effort, manufacturers, in some cases, may not seek or obtain approval for new uses since there may not be sufficient economic incentive for the product sponsor to perform the research necessary or to make application to the FDA. In other cases, of course, the research may have been carried out by the manufacturer but the new proposed use found to be unsupported.

In an attempt to be of assistance to practitioners, USP Advisory Panels have been requested to include those unlabeled indications which they believe represent reasonable, current prescribing practices based on their knowledge of the drug, the

literature, and of current prescribing and utilization practices which practitioners should be prepared to address.

These accepted unlabeled indications are identified in the category section by brackets. The unlabeled indication may be followed by a brief explanatory statement in the same bracketed paragraph. It should be noted also that in the Indications section, the Panels occasionally warn against use of a drug for reputed indications they believe to be undesirable.

The legality of the prescribing of approved drugs for uses not included in their official labeling is sometimes a cause of concern and confusion among practitioners. The appropriateness of the prescribing or dispensing of an approved drug for an unlabeled indication would ultimately be judged in accordance with normal legal principles governing professional activities such as negligence or strict liability in the event of a question of liability to an injured patient. The Federal Food, Drug, and Cosmetic Act does not prohibit practitioners from prescribing nor pharmacists from dispensing a drug product for a particular patient for an indication not contained in its approved labeling.

Pharmacology—A brief statement of pharmacologic actions includes, whenever appropriate and available, mechanism of action, actions other than the therapeutic actions, absorption, distribution in the body, protein-binding characteristics, metabolism, half-life, onset of action, time to peak concentration, peak serum concentration, time to peak effect, duration of action, and excretion. The information is not intended to be inclusive. In some cases, protein binding is expressed in general terms with ranges as follows, rather than in terms of specific percentages:

Very high: >90%
High: 65–90%
Moderate: 35–64%
Low: 10–34%
Very low: <10%

Precautions to Consider—The precautions to consider in using a specific drug as listed under this heading are not intended to provide "full disclosure" information. Instead, precautions have been selected on the basis of their common or usual clinical significance to the population as a whole. It cannot be assumed that the omission of a precaution in *USP DI* means that such a precaution may not be of clinical significance for a specific patient. In many cases, there is a lack of scientifically valid information to support inclusion in *USP DI*. As in all aspects of medical care, risk-benefit considerations must be made on an individual basis, which may, in fact, supersede general precautions to the use of any medication.

Cross-sensitivity—Potential for cross-sensitivity with other drugs is included. Warnings concerning use in patients hypersensitive to the specific agent under discussion are not included since such warnings are basic to the use of any agent and therefore must be assumed to apply in all situations.

Carcinogenicity—Where known, reference is made to the cancer-causing potential of a drug. Not all such precautions may necessarily be listed.

Tumorigenicity—Where known, reference is made to the tumor-causing potential of a drug. Not all such precautions may necessarily be listed.

Mutagenicity—Where known, reference is made to the mutagenic potential of a drug. Not all such precautions may necessarily be listed.

Pregnancy—Documented problems in humans with the use of a drug during pregnancy are included. Where appropriate, reference is also made to problems documented in animal studies even though the significance of such findings to humans may not be known. FDA-assigned pregnancy categories are included whenever available. These categories are:

A: Adequate and well-controlled studies have failed to demonstrate a risk to the fetus in the first trimester of pregnancy (and there is no evidence of risk in later trimesters).
B: Animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women.
C: Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks.
D: There is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks.
X: Studies in animals or humans have demonstrated fetal abnormalities and/or there is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience, and the risks involved in use of the drug in pregnant women clearly outweigh potential benefits.

Breast-feeding—Documented problems in humans associated with the use of a drug while breast-feeding are included. Where appropriate, reference is also made to problems documented in animal studies even though the significance of such findings to humans may not be known.

Pediatrics—Selected precautions relating to use of an agent in the pediatric patient are included. Not all precautions to such use may necessarily be listed.

Geriatrics—Selected precautions relating to use of an agent in the geriatric patient are included. Not all precautions to such use may necessarily be listed.

Drug interactions and/or related problems—Drug and/or food interactions have been selected on the basis of their potential clinical significance. Those considered to have greater significance are identified with a chevron (») to the left of the drug entry. In some cases, an interaction appearing in one monograph may not be cross-referenced in the corresponding monograph. Since each monograph is finalized individually, such inconsistencies are constantly in the process of resolution in preparation for the next update or edition of *USP DI*.

Diagnostic interference—Problems with diagnostic interference when a certain drug is taken have been selected on the basis of potential clinical significance, especially if they relate to the dispensing situation (i.e., home-use diagnostics). No attempt has been made to provide a complete listing of effects on the normal or diseased body or interferences with other tests which may be required if proper diagnosis is to be expected. The information included is broken down by interference with physiology and interference with diagnostic test results.

Medical problems—Some medical conditions, the presence of which may alter the decision to prescribe a drug for a given patient or may affect the dosage, are listed. As a general rule, the list is compiled from the approved labeling and covers precautions, warnings, and contraindications. Those conditions considered to be of greater importance are identified by a chevron (») to the left of the specific medical problem.

Patient check-ups—In order to exercise judgment in refilling prescriptions and to monitor continuing use of a medication, patient examinations that may be particularly important are listed. The list is not meant to be a complete listing of check-ups a patient may require nor is it meant to imply that all check-ups listed are necessarily required for every patient taking the medication.

Side/Adverse Effects—Selected side effects have been listed. Selection is based on seriousness (e.g., agranulocytosis), frequency of occurrence, the effect on life style (e.g., drowsiness), and/

or the likelihood that a nonthreatening side effect might cause concern in the patient if he or she were not aware that the effect might occur (e.g., rapid pulse). Wherever possible, the side effects are grouped according to reported incidence—i.e., incidence more frequent, incidence less frequent, or incidence rare; or by percentages, if available. Signs of overdose also may be included. Not all such side/adverse effects may necessarily be listed.

The side effects are listed by presenting symptom(s) with possible cause(s) in parentheses.

Patient Consultation—Current medical practice embraces the belief that patient compliance and the effectiveness of therapy can be advanced in certain clinical situations if the prescriber provides, or can ask the dispenser to provide, written drug use information of the type contained in *USP DI*. To help ensure patient understanding, the prescriber and dispenser should, in turn, translate the essence orally in words suitable to the ability of the individual patient to understand.

Suggested guidelines for patient consultation are listed. The statements marked with a chevron (») are considered to be of greatest importance. If written information is desired, the health care provider may refer to the corresponding lay language monograph in *Advice for the Patient*.

The information provided is intended to aid efforts to advance patient compliance and the effectiveness of the therapy selected by the prescriber. The information provided is not complete, but is intended to serve as a basic reminder or general guide to the health care provider who may vary or omit it in accordance with professional judgment taking into account the best interests of the patient, the request of the prescriber, or the particular circumstances involved. It is not intended as a substitute for professional judgment or to modify any legal requirements imposed on the dispenser. It serves also as a general reminder to the prescriber of the concerns of the dispenser in the dispenser-patient relationship.

Information that might pertain to all drugs, such as directions to "keep out of the reach of children" or to "notify physician if an unusual reaction occurs," is not necessarily given in the individual monograph. Instead, guidelines for general instructions on drug use are provided at the beginning of the *Advice for the Patient* volume.

Some drugs are not amenable to general rules since they may be prescribed for various purposes not necessarily known to the dispenser or person administering the drug; also, the differences in their utilization might affect the advice to be given. However, where it is clear how a drug is being utilized, it may be helpful to reinforce the prescriber's instructions or to provide such additional advice as would assist the patient.

Occasionally, a dispenser or person administering a drug may have particular knowledge of problems peculiar to the patient that justifies giving exceptional instructions. The fact that *USP DI* makes no mention of such unusual or exceptional circumstances is not intended to limit or influence professional judgment in conveying to the patient information that is deemed to be correct and proper under the circumstances.

General Dosing Information—Dosing information of a general nature which may be applicable to the usual dispensing or administration situation is included. The information is meant to supplement that dosing information included under each specific dosage form and the two sets of information must be used together.

Information relating to the treatment of overdose is also included in this section.

Dosage Forms—The following information is listed separately for each dosage form, whenever appropriate:

Summary of differences—In family monographs, a summary of differences for each individual family member is included. Not all differences are necessarily included. The fact that this section does not include certain information does not necessarily indicate that the point in question does not occur with that particular family member. It may, instead, reflect a lack of information. Users of *USP DI* must exercise caution and not use the information included in family monographs as the sole basis of comparison between agents.

Usual adult dose—The usual adult dose given for each article is that which may be expected ordinarily to produce in adults with normal renal/hepatic function, following administration in the manner indicated, at such time intervals as may be specified, the diagnostic, therapeutic, prophylactic, or other effect for which the article is recognized. The usual adult dose is intended to serve only as a guide and it may be varied in the best interests of the patient and in accordance with the variables that affect the action of the drug.

The statements of dosage in the case of capsules and tablets are in terms of the content of active ingredient and seldom represent the total weight of the capsule contents or of the tablets.

In some instances, the dosage may be stated in terms of the pharmacologically active portion (moiety) of the molecule in order to permit the prescriber or dispenser to correlate the weight equivalent for salts, esters, or other chemical forms of the drug moiety. However, it is not to be inferred that all chemical forms in which the active moiety may be presented are therapeutically equivalent. The same can be said for dosage forms; e.g., tablets vs. syrups or creams vs. ointments.

Usual adult prescribing limits—The usual adult prescribing limits subsection is intended primarily to guide the dispenser with respect to seeking confirmation of prescription orders calling for unusually small or large doses. In some cases, it may take into account some uses in addition to those implied in the statement of category. The time schedule and route of administration where given for the usual adult dose apply also to the usual adult prescribing limits unless otherwise specified.

The limits statement does not address the issue of toxicity levels but instead focuses on the generally accepted lower and/or upper ranges of dosage believed to be used in medical practice.

Usual pediatric dose—The usual pediatric dose generally given in the monograph is that which may be expected ordinarily to produce in infants and children with normal renal/hepatic function, following administration in the manner indicated, at such time intervals as may be designated, the diagnostic, therapeutic, or prophylactic effect for which the article is recognized.

The provision of the usual pediatric dose is not a recommendation or indication that the drug should be utilized in the pediatric patient, but is intended to serve only as a guide to the dispenser once the prescribing decision has been made. In connection with this decision, it is strongly recommended that the "full disclosure" information for the drug be consulted. It is to be emphasized that detoxification and excretion of many drugs, including the "inactive" ingredients in the dosage forms, are markedly different in premature and full-term newborn infants from those in older children and adults.

Strengths usually available—The statement on strengths usually available of a dosage form, given in the individual monograph, is not necessarily complete and is intended solely as information to prescribers, pharmacists, nurses, and others concerned with the manner in which dosage forms are commercially supplied.

Packaging and storage—Information concerning packaging and storage of medications as applicable to the dispenser is provided in this section. The labeling of the brand product selected may contain packaging and storage information which differs from that stated in *USP DI*.

The information included in *USP DI* is not intended to replace more definitive requirements that may be contained in the official *USP* monographs. For those dosage forms included in *USP*,

compendial requirements for packaging and storage apply to the dispenser.

For those products not covered by *USP*, the packaging and storage recommendations found in *USP DI* are usually those recommended by the manufacturer(s).

Preparation of dosage form—Instructions on constitution and/or dilution of a dosage form for administration are included. Information on the extemporaneous preparation of certain drugs, for example, for pediatric use, is also included, where deemed appropriate.

Stability—Included is information concerning beyond use dates for constituted solutions or suspensions, along with special stability problems associated with certain drug products (for example, nitroglycerin tablets). The labeling of the brand product selected may contain stability information which differs from that stated in *USP DI*.

Incompatibilities—Chemical and physical incompatibilities of certain admixtures, for example, intravenous preparations, are included, where deemed appropriate.

Label—Auxiliary information (in addition to the prescription labeling) that is suggested for consideration of placement on the actual prescription container in accordance with applicable practice requirements is specified in this section.

Recommended labeling that relates to physical properties of the product (e.g., shake well) can be considered to be universally applicable.

Suggested labeling that relates to therapy (e.g., take on an empty stomach) and would be appropriate for most, but not necessarily all patients, must be considered on an individual basis by the dispenser.

Additional information—Additional information relating to the specific drug product is included if necessary, especially as this information relates to the act of dispensing the medication.

Advice for the Patient—*Advice for the Patient* (Volume II) presents in lay language the concepts listed in the Patient Consultation guidelines of Volume I. It is meant to reinforce the oral consultation and to be provided in written form at the discretion of the health care provider. Statements that warrant a chevron (») in Patient Consultation are printed in bold type and are shaded for immediate notice in *Advice for the Patient*.

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The information presented under the section entitled *Additional Information* includes information related to unlabeled uses of the drug. This section is intended for use where the health care provider has knowledge that the medication has been prescribed for a particular purpose referred to therein. It is intended as an aid to providing individualized patient education and is not for use when providing the general population with information about the drug. Since the section may contain information which may be or seem to be contradictory or confusing to the patient receiving the drug for its labeled purposes, the health care provider should consider not including the section if photocopies of the information are given to patients routinely.

The United States Pharmacopeial Convention 1980–1985

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Panel on Veterinary Medicine—LLOYD E. DAVIS, D.V.M., PH.D., Urbana, IL; H. RICHARD ADAMS, D.V.M., PH.D., Dallas, TX; ARTHUR L. ARONSON, D.V.M., PH.D., Raleigh, NC; NICHOLAS H. BOOTH, D.V.M., PH.D., Athens, GA; GORDON L. COPPOC, D.V.M., PH.D., W. Lafayette, IN; GEORGE T. EDDS, D.V.M., PH.D., Waco, TX; SIDNEY A. EWING, D.V.M., PH.D., Stillwater, OK; PETER EYRE, B.V.M.S., PH.D., Guelph, Ontario; STUART FORNEY, R.PH., M.S., Fort Collins, CO; WILLIAM G. HUBER, D.V.M., PH.D., Mississippi State, MS; ROBERT W. PHILLIPS, D.V.M., PH.D., Fort Collins, CO; THOMAS E. POWERS, D.V.M., PH.D., Columbus, OH; I.A. SCHIPPER, D.V.M., Fargo, ND; RICHARD H. TESKE, D.V.M., Beltsville, MD.

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