Volume I

Drug Information for the Health Care Professional

USP DI®

2002

22ND EDITION

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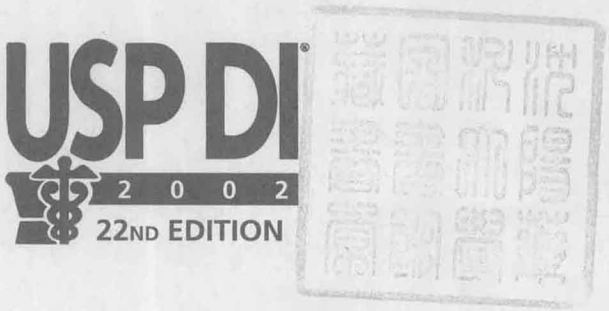
Drug Information for the Health Care Professional



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Content reviewed by the United States Pharmacopeial Convention, Inc.

NOTICE AND WARNING

Read the section, Description and Limitations of Information Included, of the "Preface" before consulting individual monographs.

Library of Congress Catalog Card Number 81-640842

ISBN 1-56363-405-8
ISSN 0740-4174

Printed by Quebecor World, Taunton, Massachusetts, 02780.
Published & distributed by MICROMEDEX, 6200 S. Syracuse Way, Suite 300, Greenwood Village, CO 80111.

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 professionals 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 resources. *USP DI* is one response to these previously unmet needs.

At the 1970 meeting of the Pharmacopeial Convention, a resolution to increase in the Pharmacopeia or in a companion volume the amount of information that would be useful to pharmacists and others was adopted. In response to this, the 1970-1975 Subcommittee on Posology and Related Information (under the chairmanship of John A. Owen, Jr., M.D., and with the staff assistance of Joseph G. Valentino) expanded the category and dose information sections 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 the particular circumstances involved.

Continuing this development, the 1975-1980 Subcommittee, under the chairmanship of Harry C. Shirkey, R.Ph., M.D., and assisted by staff member Keith W. Johnson, greatly expanded the amount and kinds of information in the *USP DI* database, focusing on that believed to enhance the safe and effective use of a medication once it was prescribed. This included drug use information relating to dispensing, administration, monitoring, and patient consultation. The work of the Subcommittee resulted in the first edition (1980) of *USP DI*. From one book in 1980, it grew to two Volumes in 1983, and three Volumes in 1989.

On September 17, 1998, the USP Board of Trustees entered into agreements with the Thomson Corporation for the sale of the *USP DI* Volume I and Volume II databases and licensing of the *USP DI* trademark. These agreements, in cooperation with MICROMEDEX, a Thomson Healthcare company, assure the continued involvement and influence of USP expert advisory panelists in developing authoritative information for use by pharmacists, physicians, other health care professionals, patients, and consumers.

USP DI is, and it always will be, a work in progress. The information is under constant revision. This twenty-second edition incorporates the experiences and comments generated by previous editions. New drug monographs and information have been added, and the existing text has been reviewed for changes and revised accordingly.

Development of the 2002 *USP DI*

The *USP DI* is a comprehensive collection of clinically relevant, established information about each drug. However, it is far more than that. It is a continuous collection of the current judgments of experts in the use of medications. The information included represents generally accepted facts about each particular medication as well as information that represents the clinical judgments of experts based on the best available evidence placed in the context of medical practice concerns.

Using the parameters established by the USP Division of Information Development Executive Committee, MICROMEDEX staff has developed or revised monographs for the drugs selected for inclusion in this twenty-second edition of *USP DI*. The information drafted has been extracted from standard, generally recognized information sources (e.g., FDA-approved labeling) and subjected to review by USP staff for consistency with *USP DI* guidelines and parameters. Portions of the text representing expert clinical judgments (e.g., off-label uses of medications) have been reviewed by the appropriate USP Advisory Panel(s) and other designated reviewers and revised accordingly until a general consensus was achieved. Proposed monographs were then made available for general public review and comment, utilizing USP's established information development processes.

The consensus can change from one edition to the next, and users of *USP DI* are encouraged to submit comments on the information in the twenty-second edition at any time to:

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Organization of *USP DI*

USP DI comprises three distinct sections. The first volume, *Drug Information for the Health Care Professional*, includes the Drug Information monographs arranged in alphabetic order. The Volume I general index includes established names, cross-references by brand names (both U.S. and Canadian), and older nonproprietary names. In addition, an indications index and appendixes presenting categories of use and other useful information are included. 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 health care 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 third volume, *Approved Drug Products and Legal Requirements*, reproduces information from the Food and Drug Administration on therapeutic equivalence and other requirements relating to drug product selection. It includes USP and NF legal requirements for labeling, storage, packaging, and quality for drugs. It also contains those portions of the federal Controlled Substances Act Regulations, the Poison Prevention Packaging Act and Regulations, and the FD&C Act provisions relating to drugs for human use, and the Current Good Manufacturing Practice Regulations that are most relevant to the physician, pharmacist, nurse, and other health care professionals.

The individual Volume I monograph covers the basic information which is applicable to that substance when used for a specific area of effect (e.g., Systemic). Information that is unique to a specific dosage form of the base substance is then included under that specific dosage form heading. To illustrate this approach, assume that DRUG X is used for its systemic effects 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 monographs 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.]

Examples of other major headings based on specific area of effect are Dental, Inhalation-Local, Intracavernosal, Mucosal-Local, Nasal-Local, Ophthalmic, Oral-Local, Otic, Parenteral-Local, Rectal-Local, Transdermal-Systemic, 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.

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

Category

Indications
- General considerations
- Accepted
- Acceptance not established
- Unaccepted

Pharmacology/Pharmacokinetics
- Physicochemical characteristics
  - Source
  - Molecular weight
  - pKa
  - Solubility
  - Partition coefficient
  - Other characteristics
- Mechanism of action/Effect
- Other actions/effects
- Absorption
- Distribution
- Protein binding
- Biotransformation
- Half-life
- Onset of action
- Time to peak concentration
- Peak serum concentration
- Time to peak effect
- Duration of action
- Elimination
  - In dialysis

Precautions to Consider
- Cross-sensitivity and/or related problems
- Carcinogenicity
- Tumorigenicity
- Mutagenicity
- Pregnancy/Reproduction
  - Fertility
  - Pregnancy
  - Labor
  - Delivery
  - Postpartum
- Breast-feeding
- Pediatrics
- Adolescents
- Geriatrics
- Pharmacogenetics
- Dental
- Surgical
- Critical/Emergency care
- Drug interactions and/or related problems
- Laboratory value alterations
  - With diagnostic test results
  - With physiology/laboratory test values
- Medical considerations/Contraindications
- Patient monitoring

Side/Adverse Effects
- Those indicating need for medical attention
- Those indicating need for medical attention only if they continue or are bothersome
- Those not indicating need for medical attention
- Those indicating need for medical attention if they occur after medication is discontinued

Overdose
- Clinical effects of overdose
- Treatment of overdose

Patient Consultation
- Before using this medication
- Proper use of this medication
- Precautions while using this medication
- Side/adverse effects

General Dosing Information
- Diet/Nutrition
- Bioequivalence information
- Safety considerations for handling this medication
- For treatment of adverse effects

Dosage forms (each separate)
- Usual adult dose
- Usual adult prescribing limits
- Usual pediatric dose
- Usual pediatric prescribing limits
- Usual geriatric dose
- Strengths usually available
- Packaging and storage
- Preparation of dosage form
- Stability
- Incompatibilities
- Auxiliary labeling
- Caution
- Additional information

Selected Bibliography

Description and Limitations of Information Included

USP DI contains selected information and takes into account practice concerns. Selection is based on what is considered by the Committee of Revision and its Advisory Panels to be practical, clinically significant information needed 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 the drugs used. Collectively, the *USP DI* is valuable when assessing the quality of care through drug utilization review programs. 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.

USP DI is not intended to be "full disclosure" information.

Readers are advised that the information in *USP DI* may contain statements that differ from those in the "full disclosure" information labeling approved or required by the United States or Canadian governments. On the other hand, readers should remember that FDA-approved full disclosure information can differ from brand to brand of the same generic drug product. It should not be inferred that the inclusion of information that is not in the approved labeling has been sought or agreed to by the manufacturer.

Selected brand names are included in the monographs as well as in the indexes of both Volumes I and II, 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 indi-

cate that the agent was judged to be inferior or inadequate. The inclusion of various brands in Volumes I and II bears no relationship to, and is not intended to affect, any applicable brand interchange requirements.

The Veterans Administration medication classification codes (primary and secondary assignments) are included at the beginning of each monograph. See the VA Medication Classification System appendix in *USP DI* Volume I for a detailed description as well as a complete listing of primary and secondary classifications.

Where appropriate, controlled substance classifications are included at the beginning of the monograph. United States schedules include:

Schedule I–No legal medical use is recognized by the U.S. Controlled Substances Act. Use of Schedule I substances for research purposes is permitted with proper registration. Schedule I substances are not included in *USP DI*.
Examples: Heroin, LSD, peyote.

Schedule II–The most stringent classification for drugs recognized by the U.S. Controlled Substances Act as having a legitimate medical use; these drugs are characterized by a very high abuse potential and/or potential for severe physical and psychic dependency. Distribution and inventory are highly controlled; prescriptions are non-refillable. Emergency telephone orders for limited quantities of these drugs are authorized but the prescriber must provide a written, signed prescription order to the pharmacy within 72 hours.
Examples: Amphetamines, anabolic steroids, meperidine, morphine, short-acting barbiturates.

Schedule III–Includes drugs having significant abuse potential, but to a lesser degree than Schedule II substances. Prescriptions can be refilled up to five times within six months after the date of issue if authorized by the prescriber. Telephone orders are permitted. Examples: Certain barbiturates not included in Schedule II, opiates in combination with other substances such as acetaminophen or aspirin.

Schedule IV–Includes drugs having a low abuse potential. Prescriptions can be refilled up to five times within six months after the date of issue if authorized by the prescriber. Telephone orders are permitted. Examples: Benzodiazepines, certain long-acting barbiturates, chloral hydrate, pentazocine, propoxyphene.

Schedule V– Includes products having the lowest abuse potential of the controlled substances. No limitations on refills other than those imposed by the prescriber. Some Schedule V products may be available without a prescription (for example, certain cough preparations and antidiarrheal preparations containing limited amounts of an opiate).

In addition to the Federal Controlled Substances Act, most states have controlled substances acts similar to the federal requirements. In some instances, the state regulations may be more restrictive. These differences are not addressed in *USP DI* monographs.

Canadian controlled substance classifications (and the designations used in this publication) include:

Narcotics (N)–Includes products containing a narcotic. Within this broad classification, there are several levels of regulatory control. These levels range from strict controls for the most abusable of the substances (for example, single-entity narcotics; products containing a narcotic with one active non-narcotic ingredient; any preparation containing heroin, hydrocodone, or oxycodone) to lesser controls for preparations containing one narcotic and two active non-narcotic ingredients and exempt codeine preparations (those containing a limited amount of codeine plus two active non-narcotic ingredients).

Controlled Drugs–Includes non-narcotic preparations with abuse potential. As with narcotics, different regulations apply depending on specific content. Examples: Amphetamines, barbiturates.

Introductory Version Monographs–Monographs on newly approved drugs based primarily on the manufacturers package insert and reviewed by selected members of the appropriate *USP DI* Advisory Panels are now included in *USP DI Volume I* and *Volume II*. Introductory Version Monographs fill the immediate need for information until a full monograph for a given drug has been developed and assessed by the advisory panels.

Category/Indications–Statements of categories of use and indications are provided for each agent.

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

Indications of use stated in manufacturers' labeling and approved by the U.S. Food and Drug Administration (FDA) or Health Canada's Therapeutic Products Directorate are generally included, as well as additional off-label indications selected as appropriate by USP Advisory Panels. These two types of indications are included under an *Accepted* subheading. An *Unaccepted* indications section identifies uses of a drug that are considered by USP Advisory Panels to be inappropriate, obsolete, or unproven. For certain drugs whose place in therapy has not been determined and the use does not clearly fall into the "Accepted" or "Unaccepted" categorization, information is included under an *Acceptance not established* subheading.

A *General considerations* subsection is included in the Indications section for some drugs, such as antibiotics, to give the reader more complete information about the use of the drug (e.g., the activity spectrum of antibiotics).

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 government'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 the clinical trials required for approval 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 necessary research or to make application to the agency. 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 off-label indications (i.e., not included in the labeling of *any* brand) 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. In certain instances, particularly life-threatening diseases for which a definitive cure is not available (e.g., some cancers), off-label uses may be included as acceptable (although experimental) because other therapy is either unavailable or has been tried and has failed.

Medically accepted off-label indications are identified in the *Indications* section, by brackets for the U.S. products and a superscript 1 for Canadian products. The off-label indication may be followed by a brief explanatory statement.

The legality of the prescribing of approved drugs for uses not included in their official labeling is sometimes a cause for concern and confusion among practitioners. The appropriateness of prescribing or dispensing an approved drug for an off-label indication would ultimately be judged in accordance with accepted legal principles governing professional activities (such as negligence or strict liability) in the event of a question of liability to an injured patient. In the U.S., 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.

Another point of concern to practitioners relates to differences in approved labeled indications for different brands of the same generic drug product. Because of the legalities involved, it is possible for different manufactured products of the same generic product to have in their labeling

different indications (as well as different precautions, side effects, dosage schedules, etc.). *USP DI* indications are not directed to a specific brand product unless a particular characteristic of a brand must be taken into account.

Evidence ratings—Evidence ratings based on study design and strength of endpoints are included in selected monographs (primarily oncology agents) to support the off-label use recommendations made by USP Advisory Panels. Once an off-label indication has been approved by the panel, the evidence rating supporting that use is placed in parentheses in Roman type (e.g.. Evidence rating: IA) in the text after the paragraph that discusses the indication, or after each indication, if they are listed in a string within a statement. Ratings are assigned based on the following scheme:

Grade level (ranked in descending order of strength)—

I: Evidence from randomized, controlled trials or meta-analyses of a group of randomized, controlled trials.

II: Evidence from well-designed, internally controlled clinical trials without randomization, from cohort or case-controlled analytic studies, preferably from more than one center, from multiple time series, or from dramatic results in uncontrolled experiments.

III: Evidence from clinical trials with low power, preliminary reports of trials in progress, opinions of respected authorities on the basis of clinical experience, descriptive studies such as case reports or series, or reports of expert committees.

Strength of Endpoints (ranked in descending order of strength) for oncology agents—

A. Total Mortality (or overall survival from a defined point in time, such as the time of randomization).

B. Cause-Specific Mortality (or cause-specific mortality from a defined point in time).

C. Carefully Assessed Quality of Life (does not include reports of symptoms or toxicity).

D. Indirect Surrogates (includes disease-free survival, progression-free survival, tumor response rate).

Pharmacology/Pharmacokinetics—A brief statement of physicochemical characteristics and pharmacologic actions includes, whenever appropriate and available, source, molecular weight, pKa, solubility, partition coefficient, mechanism of action, actions other than the therapeutic actions, absorption, distribution in the body, protein-binding characteristics, biotransformation, half-life, onset of action, time to peak concentration, peak serum concentration, time to peak effect, duration of action, and elimination. The information is not intended to be all 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 and/or related problems—Where known, potential for cross-sensitivity with other drugs is included.

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/Reproduction—Documented problems in humans with the use of a drug during pregnancy are included. Where appropriate, information is included on fertility, pregnancy, labor, delivery, and postpartum effects. In addition, reference is 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, if the drug is needed in a life-threatening situation or for a serious disease for which safer drugs cannot be used or are ineffective.

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 relevant to such use may necessarily be listed. If no information about the use of a drug in the pediatric patient is known, this is so stated.

Adolescents—Selected precautions relating to use of an agent in the adolescent patient are included. Not all precautions relevant 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 relevant to such use may necessarily be listed. If no information about the use of a drug in the geriatric patient is known, this is so stated.

Pharmacogenetics—Selected precautions relating to genetic factors and potential responses to drugs are included. Not all such potential effects may necessarily be listed.

Dental—Selected precautions relating to potential dental effects of an agent are included. Not all such potential effects may necessarily be listed.

Surgical—Selected precautions relating to potential effects of an agent on surgery are included. Not all precautions relevant to surgery may necessarily be listed.

Critical/Emergency care—Selected precautions relating to potential effects of an agent in a critical/emergency care situation are included. Not all such precautions 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 revision of the monograph.

Laboratory value alterations—This section includes effects of the drug on laboratory test values. No attempt has been made to provide a complete listing of effects on the normal or diseased body or interferences with other tests that may be required if proper diagnosis is to be expected. The information included in this section is broken down into two subsections:

With diagnostic test results—Includes changes in laboratory test values caused by effects of the drug in the body or on the test materials or procedure that may produce inaccurate results (e.g., diagnostic tests for which the results may be false-positive or false-negative in patients receiving the drug).

With physiology/laboratory test values—Includes changes in laboratory test values that may occur because of the physiologic effects of the drug (for example, increases or decreases in serum electrolytes).

Effects listed have been selected on the basis of potential clinical significance. The list is not necessarily inclusive.

Medical considerations/Contraindications—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. Contraindications that are considered to be absolute, except under special circumstances, are listed first. Relative contraindications are included for those problems requiring risk-benefit consideration.

Patient monitoring—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 the 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 are listed. Selection is based on seriousness (e.g., agranulocytosis), frequency of occurrence, effect on life style (e.g., drowsiness). and/or likelihood that a nonthreatening side effect might cause concern to the patient if he or she were not aware that the effect might occur (e.g., rapid pulse). Wherever possible, side effects are grouped according to reported incidence—i.e., incidence more frequent, incidence less frequent, or incidence rare; or by percentages, if available. Not all such side/adverse effects may necessarily be listed.

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

Overdose—This section includes selected information on therapeutic and toxic concentrations of the drug, time to onset of overdose symptoms, clinical effects of overdose, and treatment of overdose.

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 asks 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 of this information in words suitable to the ability of the individual patient to understand.

Prior to providing oral consultation, health care professionals should apprise themselves of the entire monograph for the indicated medication. The patient consultation section is provided as a reminder, highlighting a limited, selected number of items peculiar to the medication for oral discussion and, in general, assumes more complete written information can be made available.

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.

Some drugs are not amenable to general rules since they may be prescribed for various purposes not necessarily known to the dispenser, to the person administering the drug, or to other physicians caring for the patient; 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 and guidelines relating to diet/nutrition and bioequivalence are included, where appropriate. The information is meant to supplement the dosing information included under each specific dosage form, and the two sets of information must be used together.

Information relating to safety considerations for handling a medication and the treatment of adverse effects 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 agent is that which may ordinarily be expected 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 agent is recognized. The usual adult dose is intended to serve only as a guide, it may be varied in the best interests of the patient, and in accordance with the variables that affect the action of the drug. Where appropriate, information relating to dosing in a patient who has renal/hepatic function impairment is included.

The statements of dosage in the case of capsules and tablets are in terms of the content of active ingredient and rarely 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. Neither are different dosage forms administered by the same route always therapeutically equivalent, 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 ordinarily be expected 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 agent is recognized. Where appropriate, information relating to dosing in a patient who has renal/hepatic function impairment is included.

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. It should be emphasized that metabolism and elimination of many drugs, including the "inactive" ingredients in the dosage forms, are markedly different in full-term newborn infants, and even more so in premature infants, from those in older children and adults.

Usual pediatric prescribing limits—The usual pediatric 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 pediatric dose apply also to the usual pediatric prescribing limits unless otherwise specified.

Usual geriatric dose—A usual geriatric dose statement is included if current knowledge allows. It is to be emphasized that metabolism and elimination of many drugs, including the "inactive" ingredients in the dosage forms, may be markedly different in the geriatric patient.

The provision of the usual geriatric dose is not a recommendation or indication that the drug should be utilized in the geriatric patient. It 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.

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

If a specific drug product is known to contain sulfites, large amounts of lactose, or other inactive ingredients known to cause allergic reactions in large numbers of patients, this information has been included for selected medications. The inactive ingredient listings are not all inclusive. The fact that a product listing does not include identification of inactive ingredients does not necessarily mean that the product is free of potentially offending inactive ingredients.

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 additional or other packaging and storage information specific to that product.

The information included in this section 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 reconstituted 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 specific stability information which differs from that stated in *USP DI*.

Incompatibilities—Chemical and physical incompatibilities of certain admixtures (e.g., intravenous preparations) are included, where deemed appropriate.

Auxiliary labeling—Auxiliary information that is suggested for consideration of placement on the actual prescription container (in addition to the prescription labeling) 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" for suspensions) 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.

Caution—Information on potential medication errors, where known, and steps to help minimize occurrence of such errors are included as appropriate.

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 (Volume II)—*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. In general, statements that warrant a chevron (») in Patient Consultation are printed in *italic* type for immediate notice in *Advice for the Patient*.

The information presented under the section entitled *Additional Information* includes information related to medically accepted off-label 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 this section if photocopies of the information are given to patients routinely.

Approved Drug Products and Legal Requirements (Volume III)—The United States Pharmacopeial Convention is the publisher of the *United States Pharmacopeia* and the *National Formulary*. These texts are recognized as official compendia by the pharmacy and medical professions. They contain standards, specifications, and other requirements relating to drugs and other agents used in medical and pharmacy practice that may be enforceable under various statutes. These requirements are applicable not only when drugs are in the possession of the manufacturer, but at the practice level as well.

Although the standards continue to be applicable when drugs are dispensed or sold, it must also be recognized that most prescriptions today are filled with manufactured products and for the most part physicians and pharmacists no longer routinely compound or analyze drug products. On the other hand,. dispensers need to be aware of the quality attributes of products, their packaging and storage requirements, and the other applicable standards to which legal consequences may attach

In recognition of this need, Volume III provides abstracts of *USP-NF* standards. Similarly, selected portions of the *USP-NF* General Notices and Chapters that are deemed to be especially relevant are reprinted in Volume III.

The incorporation of these official *USP-NF* materials into *USP DI* is for informational purposes only. Because of varying publication schedules, there may occasionally be a time difference between publication of revisions in the *USP-NF* and the appearance of these changes in *USP DI*. *Readers are advised that only the standards as written in the* ***USP-NF*** *are regarded as official.*

The *USP-NF* material included in *USP DI* is not intended to represent nor shall it be interpreted to be the equivalent of or a substitute for the official *United States Pharmacopeia and/or National Formulary*. In the event of any difference or discrepancy between the current official *USP* or *NF* standards and the information contained herein, the context and effect of the official compendia shall prevail.

Volume III also contains federal requirements relevant to the dispensing situation, including:

- the entire text of FDA's "Orange Book," *Approved Drug Products with Therapeutic Equivalence Evaluations;*
- separate listings of B-rated drugs from the FDA "Orange Book" and pre-1938 drugs ("grandfathered" drugs not included in the "Orange Book");
- selected portions of the federal Controlled Substance Act Regulations:
- the federal Food, Drug and Cosmetic Act requirements as they relate to human drugs, including the recent drug diversion and sampling amendments;
- FDA's Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals.

Appendixes

To help the user of *USP DI,* numerous appendixes have been included in both Volume I and Volume II.

Volume I—Volume I includes the following additional material as appendixes:

Additional Products and Indications (Appendix I)—Newly marketed and other products not included in the main text of *USP DI* are referenced in this appendix in order to provide as much useful information as possible. The information included has not gone through the *USP DI* review process and is based simply on the product's package insert.

Selected List of Drug-induced Effects (Appendix II)—A list of selected drug-induced side effects has been compiled for use primarily in conjunction with the drug interactions section of *USP DI* monographs. The listing of drugs is not meant to be inclusive.

Therapeutic Guidelines (Appendix III)—This appendix provides selected general therapeutic guidelines for the health care professional.

VA Medication Classification System (Appendix IV)—The Veterans Administration Medication Classification system was developed to provide a systematic and management approach to the classification of medications, investigational drugs, prosthetic items, and expendable supplies for hospital patients. Primary and secondary VA codes are included in each *USP DI* monograph and in this appendix. In addition, codes for new products are included in the Additional Products and Indications chart (Appendix I).

The Medicine Chart (Appendix V)—The Medicine Chart presents photographs of many of the most frequently prescribed medicines in the United States. In general, commonly used brand names and a representative sampling of generic products have been included. Only solid oral dosage forms (tablets and capsules) have been included. Since color and size variations may exist and since product changes may have subsequently been adopted by a manufacturer, the chart should be used only as an initial guide, with verification of product identity being made before any further actions are taken.

Poison Control Center Listing (Appendix VI)—Includes a listing of certified regional U.S. poison control centers.

Combination Cross-reference Listing (Appendix VII)—This appendix provides a listing of the therapeutically active ingredients found in combination products included in the 2002 edition of *USP DI* along with a cross-reference to the title of the monograph where the specific combination product can be found.

Orphan Drug and Biological Listing (Appendix VIII)—As a service to users of the *USP DI* data base, this appendix reproduces the list of orphan drug and biological designations as issued by thc U.S. Food and Drug Administration. This list includes the names of the substances, designated uses, and the names and addresses of sponsors. The information is inclusive for all orphan drug/biological designations made since the inception of the program. Some of these products have since been fully approved by the Food and Drug Administration and are currently being marketed. Others remain under investigation or are no longer being actively studied. The current status of each orphan drug/biological, where known, is included in the listing.

It should be noted that the names used in this listing for products that have not been approved for marketing may not be the established names approved by FDA for these products if they are eventually approved for marketing. Since these products are investigational, some may not have been reviewed for purposes of assigning the most appropriate name.

The USP-Practitioners' Reporting Network (Appendix IX)—To assist health care professionals in their responsibility to report reactions to or problems with medications, the appendix appropriate reporting forms are reproduced in this appendix.

Excluded Monographs (Appendix X)—This appendix provides a listing of monographs that are not included in this printed edition of *USP DI Volume I.* These monographs are still available by accessing the *USP DI* Updates Online website. See the back cover for details on how to access the website.

Volume II—As in Volume I, The Medicine Chart is included in Volume II in the front of the book. Also included are sections on General Information about Use of Medicines, Avoiding Medicine Mishaps, Getting the Most Out of Your Medicines, and About the Medicines You Are Taking.

In addition, Volume II includes:

*Additional Products and Uses (*Appendix I)—Newly marketed and other products not included in the main text of *USP DI* are referenced in this appendix in order to provide as much useful information as possible. The information included has not gone through the *USP DI* review process and is based simply on the product's package insert.

Poison Control Center Listing (Appendix II)—Includes a listing of certified regional U.S. poison control centers.

USP People (Appendix III)—This appendix lists USP Officers, Board of Trustees, Committees, Panels, and Members.

Categories of Use (Appendix V)—A listing of drugs by their category of use is included in this appendix only as a useful reference. It should not be used to make decisions concerning the appropriateness of therapy. In addition, the drugs included under each entry should not be considered interchangeable for any given patient since in many instances the drugs will differ significantly with regard to effectiveness, seriousness of side effects, and other critical considerations.

Pregnancy Precaution Listing (Appendix VI)—To assist the user of the *USP DI* database, this appendix provides a list of those *USP DI* monographs that have a specific precaution included as to use during pregnancy. Since the clinical significance of the precaution varies from drug to drug, the individual monograph should be consulted for additional information. The absence of a drug from the list is not meant timply that the drug is necessarily known to be safe for use in pregnant patients.

Breast-feeding Precaution Listing (Appendix VII)—This appendix provides a list of those *USP DI* monographs that have a specific precaution included as to use of a drug while breast-feeding. Since the clinical significance of the precaution varies from drug to drug, the individualmonograph should be consulted for additional information. The absence of a drug from the list is not meant to imply that the drug is necessarily known to be safe for use in women who are breast-feeding.

Volume II also includes a glossary of drug and medical terminology to help the consumer better understand the information presented in the *Advice for the Patient* monographs.

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The information presented in this text represents an ongoing review of the drugs contained herein and represents a consensus of various viewpoints expressed. The individuals listed below have served on the USP Expert Committees for the 2000-2005 revision period and have contributed to the development of the 2002 USP DI database. Such listing does not imply that these individuals have reviewed all of the material in this text or that they individually agree with all statements contained therein.

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