1983 USP DI

Drug Information for the Health Care Provider

C.V. Mosby Company

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Foreword

Spread the Words

This book is not only important in itself but is the basis of a system in which every health care practitioner is enabled and encouraged to be a part: the healthy exchange of drug information between a practitioner and a patient.

- USP DI is now in two parts: the practitioner's volume and the patient language volume. Extra copies of the patient language volume can be made available in the doctor's office and at the pharmacy counter and the nursing station thereby providing an opportunity for the patient to read about drugs he or she is already taking, as well as to read about the drug then being prescribed or dispensed or administered.
- Photocopy privileges are granted the practitioner without further request when copies are provided to a patient without charge. (See copyright notice.)
- Collections of monographs about the drugs used in a particular disease condition can be prepared, along with lay language information about the disease. For example, the antihypertensive drug monographs have been printed in a booklet prepared by USP in cooperation with the National High Blood Pressure Education Program. A book containing the special information about all of the drugs in regard to pregnancy, delivery, and breast-feeding is being prepared in cooperation with several organizations interested in those special situations.

Educational and health care organizations interested in other special conditions are encouraged to consider such collections of monographs to accompany a patient language message about the disease condition, putting the use of the drugs into perspective; or, such organizations are encouraged to adopt existing USP DI publications for use in their patient education programs as has been done by the American Academy of Family Physicians and the American Society of Internal Medicine.

The American Medical Association is preparing to launch a massive program of Patient Medication Information (PMI) leaflets for the most frequently used drugs, taking portions of the text from the USP DI. USPC will prepare copy from its computerized USP DI information base, tailored to AMA specifications.

Such USPC services are not limited to the USA. A similar program is already underway by the Canadian Pharmaceutical Association in cooperation with the Health Protection Branch, Health and Welfare Canada.

Tailoring the information to specific practice situations and to specific systems for handling the copies may be the key to making the information more widely available.

Other information providers are challenged to consider the special systems by which drug use information might be provided in the circumstances common to their clientele. USPC will be more than happy to cooperate. The USP organization is best suited to reaching a national consensus on the words to describe the effects of the drugs. But the words don't help the practitioner or the patient if they're left in the USP computer. The specialty organizations of health care providers and their commercial suppliers can do far more than USP to spread the words.

William M. Heller
Executive Director, USPC

Rockville, Maryland
June 1, 1982

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 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 will always be, a work in progress. The information is under constant revision. The 1983 edition incorporates the experiences and comments generated by the 1980 and 1981 editions. The text has been reviewed for changes and revised accordingly.

USP DI is planned to become 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.

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 reviewers and are revised accordingly. Revised monographs are then published for general public review and comment in *USP DI Review*.

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.

Users of *USP DI* are encouraged to submit comments to:

USP
Drug Information Division
12601 Twinbrook Parkway
Rockville, Maryland 20852

Organization of USP DI

USP DI comprises two distinct sections. The first volume includes the DI monographs arranged in alphabetic order. Indexed by established names, categories of use, and selected medical information such as pregnancy warnings and breast-feeding warnings, it includes 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 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* 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 monograph:

- Category
  - Indications
- Pharmacology
  - Mechanism of action
  - 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
  - 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
- Dosage forms (each separate)
  - Usual adult dose
  - Usual adult prescribing limits
  - Usual pediatric dose
  - Strengths usually available
  - Packaging and storage
  - Stability
  - Label
  - Note to the dispenser
  - Additional information

[Note: A "note" is used under any heading or subheading if special explanations, statement of exceptions, or other qualifying information is necessary.]

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 and is therefore not appropriate for use in making prescribing decisions unless supplemented by other references where necessary.

USP DI contains selected information. Selection is based on what is considered 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 also 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 *Advice for the Patient* monographs as well as in the index to 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.

The inclusion of any drugs in respect to which patent or trademark rights may exist shall not be deemed and is not intended as a grant of, or authority to, exercise any right or privilege protected by such patent or trademark. All such rights and privileges are vested in the patent or trademark owner and no other person may exercise the same without the express permission, authority, or license secured from such a patent or trademark owner

Category—A statement of category of use and specific indications is provided for each article as useful information. It indicates the medical basis for recognition and generally represents an application of the best known pharmacologic action of the article or of its active ingredient. The statement is not intended to limit in any way the choice or use of the article nor to indicate that it has no other activity or utility. Categories of use stated in labeling approved by the Food and Drug Administration are included; unlabeled categories of use are included when, in the opinion of USP Medical Advisory Panels, such uses are believed to represent current prescribing practices which the practitioner should be prepared to address.

Pharmacology—A brief statement of pharmacologic actions, whenever appropriate and available, includes mechanism of action, 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. Protein binding is expressed as follows, rather than in terms of 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 that 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.

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 of the monographs 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.

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 only as a basic reminder or general guide to the health care provider who may vary or omit it in accordance with 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 his or her 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.

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 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.

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 commonly 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 any more definitive requirements contained in the official *USP* monographs. For those dosage forms included in *USP*, compendial requirements for packaging and storage apply to the dispenser. Although not specifically stated in each *USP DI* monograph, this includes storage in well-closed containers, as defined therein by that term.

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

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

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.

Note to the dispenser—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—The *Advice for the Patient* volume 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*.

Physicians, dentists, pharmacists, nurses, or other health care practitioners are given permission to reproduce a limited number of one or more pages of advice but only when for direct distribution, without charge, to their patients or clients receiving the prescribed drug, provided that such reproduction shall include the copyright notice on each page.

When unlabeled uses are included, they are presented under a heading of Additional Information. The health care provider must decide the appropriateness of providing such information, depending on the specific needs of the individual patient.

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