

**AMA
DRUG
EVALUATIONS**
FOURTH EDITION

Prepared by the
AMA
DEPARTMENT
OF DRUGS

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FOURTH EDITION



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DEPARTMENT
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In Cooperation with the
**American Society for
Clinical Pharmacology
and Therapeutics**



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Preface

The fourth edition of *AMA Drug Evaluations* (AMA-DE) continues the successful joint cooperative effort between the AMA Department of Drugs and the American Society for Clinical Pharmacology and Therapeutics (ASCPT). As in the previous edition, the text for the fourth edition was written by the professional staff of the AMA Department of Drugs or outside contributors, reviewed by several hundred distinguished consultants, and then subjected to final review by members or other selected experts for the American Society for Clinical Pharmacology and Therapeutics. Thus, this publication is a joint scientific contribution to the field of applied therapeutics by the AMA and ASCPT. The introductions and evaluations contained therein represent a distillation of the current scientific literature plus the combined wisdom of many experienced clinicians.

Since its first edition in 1971, the goal of AMA-DE has been to provide physicians and other health care professionals with up-to-date, unbiased information on the *clinical* use of drugs. Thus, AMA-DE is not intended to serve as a textbook of basic pharmacology but, rather, as a reference source for practical drug therapy. Basic pharmacologic information, pharmacokinetics, and pathogenesis of disease are presented only to the extent deemed necessary to understand drug use in patients.

Probably no field of medicine changes as rapidly as drug therapy. Thus, even though only three years have elapsed since the last edition, most of the text of this fourth

edition has been completely rewritten or rigorously revised to reflect the latest information and expert consensus on the most effective use of therapeutic agents. Evaluations of 57 new drugs marketed since the third edition, plus expanded information on important investigational agents and new uses of older drugs, have been added. There is a reorganized table of contents for the 87 chapters, including new chapters on Immunomodulators, Antiviral Agents, Parenteral and Enteral Nutrition, and Agents Used to Treat Infertility.

The format of AMA-DE has evolved considerably since the first edition. In an effort to be responsive to reader comment and criticism, a questionnaire was included with later press runs of the last edition. The very gratifying response by many thousands of readers has provided many suggestions for improving the format and usefulness of this fourth edition. The page layout and typography have been redesigned for ease of reading and quick reference. This edition contains expanded general discussion on use of drugs in special groups (pediatric patients, geriatric patients, pregnant and lactating women, patients with renal impairment), adverse reactions, drug interactions, and drug response variation. An innovation is the use of outlines at the beginning of each chapter to aid the reader in determining chapter organization quickly. The use of tables has also been expanded for easy access to information. The multiple indexes of previous editions have been consolidated into a single comprehensive index that includes

drug names (both generic and trademark), indications, and adverse reactions. The index also includes selected Canadian trade names with their nonproprietary names. There is also an expanded listing of available dosage forms and sizes of generic products in addition to trademark preparations. Finally, in response to requests by users of previous editions, a listing of selected references has been added to the end of the chapters; this should not be interpreted as a bibliography of the literature consulted in preparation of the text but merely a guide for readers interested in further reading.

AMA-DE continues to describe uses, routes of administration, or dosages that may not be found in the "package insert." FDA-approved labeling limits the use of drugs for purposes of marketing and advertising but does not constrain a physician's

use of the drug for individual patients. Furthermore, FDA may not be current in approving new uses, routes, or dosages of older drugs. Accordingly, AMA-DE describes all scientific, recognized uses of drugs, irrespective of their status in approved labeling in the "package insert."

The American Medical Association is grateful to the American Society for Clinical Pharmacology and Therapeutics for invaluable assistance rendered in the preparation of this book and hopes that AMA-DE will continue to be a valuable and useful reference source for the medical profession and others working in the field of medical care.

James H. Sammons, M. D.
Executive Vice President
American Medical Association

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Donald R. Bennett, M.D., Ph.D.
Charles B. Clayman, M.D.
Mary Ellen Kosman, Ph.D.
John Reed Lewis, Ph.D.
Barbara F. Murphy, M.S.
Carol M. Proudfit, Ph.D.
Donald O. Schiffman, Ph.D.

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Marilyn A. Krause
Sandra McVeigh
Marsha Meyer
Beverly J. Rodgers
Patti J. Stone
Yuriko Takemoto
Wanda Wade

Special Contributors

Saul Krugman, M.D.
New York University Medical Center
New York
Hans B. Nevinny, M.D.
Weiss Memorial Hospital
Chicago
John A. Robinson, M.D.
Loyola University Medical Center
Maywood, Illinois

Charles W. Roscoe, Ph.D.
University of the Pacific
Stockton, California
Edward M. Sellers, M.D., Ph.D.
Addiction Research Foundation
University of Toronto
Toronto, Canada
Professor Doctor M. Verstraete
Catholieke Universiteit Leuven
Leuven, Belgium

Consultants

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Portland, Oregon
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Iowa City, Iowa
Steven M. Teutsch, M.D.
Atlanta, Georgia
Miles M. Weinberger, M.D.
Iowa City, Iowa
Anne C. Wentz, M.D.
Memphis, Tennessee
Stanford Wessler, M.D.
New York, New York
Philip L. White, Sc.D.
Wilmette, Illinois
Colin R. Woolf, M.D., F.R.C.P.
Toronto, Canada
Melvin D. Yahr, M.D.
New York, New York
Hyman J. Zimmerman, M.D.
Washington, D.C.

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JOHN C. BALLIN, Ph.D.
Director
Department of Drugs

New Drugs Evaluated For Fourth Edition

Drug

Asparaginase [Elspar]
 Azatadine Maleate [Optimine]
 Baclofen [Lioresal]
 Beclomethasone Dipropionate
 [Beclovent, Vanceril]
 Bretylium Tosylate [Bretylol]
 Bromocriptine Mesylate [Parlodel]
 Butorphanol Tartrate [Stadol]
 Calcitriol [Rocaltrol]
 Carboprost Tromethamine
 [Prostin/M15]
 Carmustine [BiCNU]
 Cefaclor [Ceclor]
 Cefadroxil Monohydrate [Duricef]
 Cefamandole Nafate [Mandol]
 Cefoxitin Sodium [Mefoxin]
 Chlorhexidine Gluconate
 [Hibiclens]
 [Hibitane Tincture]
 Cimetidine [Tagamet]
 Cisplatin [Platinol]
 Clemastine Fumarate [Tavist]
 Colestipol Hydrochloride [Colestid]
 Cyclobenzaprine Hydrochloride [Flexeril]
 Desmopressin Acetate [DDAVP]
 Desoximetasone [Topicort]
 Dextranomer [Debrisan]
 Diflorasone Diacetate [Florone]
 Diloxanide Furoate [Furamide]
 Dinoprostone [Prostin Ez]
 DMSO (dimethyl sulfoxide) [Rimso-50]
 Disopyramide Phosphate [Norpace]
 Dobutamine Hydrochloride [Dobutrex]

Indication or Classification

Antineoplastic
 Antihistamine
 Skeletal muscle relaxant
 Adrenal corticosteroid
 for bronchoconstriction
 Antiarrhythmic
 Dopaminergic
 Analgesic
 Vitamin D metabolite
 Uterine stimulant
 Antineoplastic
 Cephalosporin
 Cephalosporin
 Cephalosporin
 Cephamycin
 Dermatologic
 Antimicrobial skin cleaner
 Preoperative preparation of
 patient's skin
 Gastrointestinal ulcer therapy
 Antineoplastic
 Antihistamine
 Hypolipidemic
 Skeletal muscle relaxant
 Antidiuretic
 Topical corticosteroid
 Nonenzymatic preparation for
 wound debridement
 Topical corticosteroid
 Amebicide
 Uterine stimulant
 Interstitial cystitis
 Antiarrhythmic
 Inotropic agent

Etidocaine Hydrochloride [Duranest]
 Etidronate Disodium [Didronel]
 Hepatitis B Immune Globulin
 [H-BIG, Hep-B-Gammagee]
 Hymenoptera Venom Allergenic Extracts
 [Albay, Pharnalgen]
 Intralipid
 Lactulose [Cephulac, Duphalac]
 Lomustine [CeeNU]
 Loperamide Hydrochloride [Imodium]
 Lorazepam [Ativan]
 Metoclopramide [Reglan]
 Metoprolol Tartrate [Lopressor]
 Microfibrillar Collagen Hemostat
 [Avitene]
 Minoxidil [Loniten]
 Nalbuphine [Nubaine]
 Pneumococcal Vaccine, Polyvalent
 [Pneumovax]
 Prazepam [Verstran]
 Prazosin Hydrochloride [Minipress]
 Probucol [Lorelco]
 Protirelin [Relefact TRH, Thypinone]
 Sincalide [Kinevac]
 Somatropin [Asellacrin]
 Sulindac [Clinoril]
 Tamoxifen Citrate [Nolvadex]
 Ticarcillin Disodium [Ticar]
 Ticrynafen [Selacryn]
 Timolol Maleate [Timoptic]
 Trimipramine Maleate [Surmontil]
 Urokinase [Abbokinase]
 Valproic Acid [Depakene]
 Vidarabine [Vira-A]

Local anesthetic
 Paget's disease
 Antiserum

 Immunotherapeutic agent

 Intravenous fat emulsion
 Portal-systemic encephalopathy
 Antineoplastic
 Antidiarrheal
 Antianxiety
 Gastrointestinal motility stimulant
 Antihypertensive
 Hemostatic

 Antihypertensive
 Analgesic
 Immunologic

 Antianxiety
 Antihypertensive
 Hypolipidemic
 Thyroid function diagnosis
 Gastrointestinal agent
 Human growth hormone
 Antiarthritic
 Antineoplastic
 Penicillin
 Antihypertensive-Diuretic
 Antiglaucoma drug
 Antidepressant
 Anticoagulant
 Anticonvulsant
 Antiviral

Investigational Drugs Discussed in Fourth Edition

Drug	Indication or Classification
Anti-Human Lymphocyte Globulin	Immunomodulator
Azacididine	Antineoplastic
Captopril	Antihypertensive
Chenodiol (Chenodeoxycholic Acid) [Chenix]	Callstone therapy
Clofazimine [Lamprene]	Antimycobacterial (leprosy)
Daunorubicin Hydrochloride	Antineoplastic
Deprenyl	Antiparkinsonism
Domperidone	Antiemetic
Etomidate	General anesthetic (intravenous)
Flunitrazepam [Rohypnol]	General anesthetic (intravenous)
Ftorafur	Antineoplastic
Haemophilus Influenzae Type B Vaccine	Vaccine
Hepatitis B Vaccine Inactivated	Vaccine
Hexamethylmelamine	Antineoplastic
Isoflurane [Forane]	General anesthetic (inhalant)
Isophosphamide	Antineoplastic
Isotretinoin (13- <i>cis</i> -retinoic acid)	Dermatologic (acne)
Levamisole	Immunomodulator
Mitolactol	Antineoplastic
Penfluridol [Semap]	Antipsychotic
Porfiromycin	Antineoplastic
Propiram Fumarate [Dirame]	Analgesic
Razoxane	Antineoplastic
Ritodrine	Uterine relaxant
Saralasin	Antihypertensive
Semustine	Antineoplastic
Streptozocin [Zanosar]	Antineoplastic
Teprotide	Antihypertensive
Tetrabenazine	Antichorea
Varicella-Zoster Vaccine Live Attenuated	Vaccine
Zomepirac Sodium [Zomax]	Analgesic

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