

CPS

Compendium of Pharmaceuticals and Specialties

Thirty-fourth Edition

1999

The Canadian Reference
for Health Professionals

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E-mail requests@cdnpharm.ca

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CPS

Compendium of Pharmaceuticals and Specialties

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| Published by | Canadian Pharmacists Association Ottawa, Ontario, Canada |
| President | Garry Cruickshank, BScPharm |
| Executive Director | Leroy Fevang, BScPharm, MBA |
| Publisher | Leesa D. Bruce |
| Editor-in-Chief | M. Claire Gillis, BSc(Pharm) |
| Associate Editors | Louise Welbanks, BScPhm Diane Bergeron, BPharm Marline Cormier-Boyd, BSc(Pharm) Frances Hachborn, BScPhm Barbara Jovaisas, BSc(Pharm) Sandra Pagotto, BSP Carol Repchinsky, BSP |
| Senior Assistant Editor | Roxanne Bisson |
| Production Coordinator | Rita Tremblay |
| PRS Coordinator | Julie Lévesque |
| Assistant Editors | Dianne Baxter Robin McIntosh, BA |
| Editorial Assistant | Murielle Danis |
| Manager, Book Production | Darquise Leblanc |
| Typesetters | Bob Heathorn, Lucienne Prévost, Kathleen Régimbald |

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PREFACE

The ***Compendium of Pharmaceuticals and Specialties (CPS)*** is editorially compiled and produced by the staff of the Canadian Pharmacists Association for the benefit of all health professionals.

Users are advised that the information provided in the *CPS* is not exhaustive. Other sources may contain additional necessary information for safe use of the product.

Changes to monographs contained in the *CPS* received by the publisher after established deadlines are not included in this edition.

The *CPS* editors work closely with the *CPS* Editorial Advisory Panel, the Therapeutic Products Programme, Health Canada, and the pharmaceutical industry.

The editors acknowledge the collaborative effort of the many contributors and reviewers listed on page viii.

The editors express their thanks to all manufacturers and distributors who have cooperated by supplying information, offering suggestions and reading proofs. We extend an appreciation to the users of the *CPS* who forwarded constructive suggestions for amendments to the text and revisions in the format.

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EDITORIAL ADVISORY PANEL

B.R. Schnell, PhD (Chairman)

Executive Director
Canadian Council for Accreditation of Pharmacy Programs
Saskatoon

J. Gray, MD, FRCPC

Professor of Medicine and Pharmacology
Faculty of Medicine
Dalhousie University, Halifax

R. Grymonpre, BScPharm, PharmD

Associate Professor, Faculty of Pharmacy
University of Manitoba, Winnipeg

K.L. MacCannell, MD, PhD, FRCPC, FACP

Professor of Medicine; Chief of Gastroenterology
Professor of Pharmacology/Therapeutics
University of Calgary

P.J. McLeod, MD, FRCPC, FACP

Professor of Medicine, Pharmacology and Therapeutics
McGill University, Montreal; Senior Physician
Montreal General Hospital

C.J. Patterson, MD, FRCPC, FACP

Professor
Division of Geriatric Medicine
McMaster University, Hamilton, Ontario

R.G. Peterson, MD, PhD, MPH

Professor and Chairman
Department of Paediatrics, Professor of Pharmacology
University of Ottawa; Medical Director
Ontario Provincial Poison Information Centre
Children's Hospital of Eastern Ontario, Ottawa

J. Ruedy, MD, FRCPC

Dean, Faculty of Medicine
Dalhousie University, Halifax

I. Sketris, PharmD, MPA (HSA)

Professor, College of Pharmacy
Dalhousie University, Halifax; Clinical Specialist
Department of Pharmaceutical Services
Queen Elizabeth II Health Sciences Centre, Halifax

Participating Observers

M. Brown, PharmD

Pharmaceutical Manufacturers Association of Canada Delegate
Executive Director, Government Affairs
Astra Pharm Inc., Mississauga, Ontario

M. Spino, BScPhm, PharmD

Canadian Drug Manufacturers Association Delegate
Sr. Vice-President, Scientific Affairs, Apotex, Inc., Weston, Ontario
Professor, Faculty of Pharmacy, University of Toronto

M.C. Gillis, BSc(Pharm) (Secretary)

Editor-in-Chief
Canadian Pharmacists Association, Ottawa

CONTRIBUTORS/REVIEWERS

M. Ackerman, MD, FRCPC

Heart and Stroke Foundation of Canada
Emergency Cardiac Care Subcommittee
Burlington, Ontario

D.R. Anderson, MD, FRCPC

Assistant Professor of Medicine,
Dalhousie University, Halifax
Division of Hematology
Queen Elizabeth II Health Sciences Centre, Halifax

C. Bayliff, PharmD

Clinical Coordinator of Pharmacy Services
London Health Sciences Centre, Victoria Campus
London, Ontario

M. Bédard, PharmD

Drug Information Specialist
The Ottawa Hospital, General Campus

M. Bodie-Collins, RN, BScN

Travel Medicine Advisor
Travel Medicine Program
Office of Special Health Initiatives
Health Canada, Ottawa

J. Bruni, MD, FRCPC

Head, Division of Neurology
Wellesley Hospital, Toronto

P. Camfield, MD, FRCPC

Professor and Head, Department of Pediatrics
Dalhousie University
IWK Grace Health Centre, Halifax

N. Campbell, MD, FRCPC

President, Canadian Coalition for High Blood
Pressure Prevention and Control
Department of Medicine
University of Calgary

S.G. Carruthers, MD, FRCPC

Richard Ivey Professor and Chair
Department of Medicine, University of Western Ontario
Chief of Medicine
London Health Sciences Centre, London, Ontario

J. Courtemanche, BScN(Ed)

Secretary
Canadian Association of Poison Control Centres
Children's Hospital of Eastern Ontario, Ottawa

S. Cowan, BScPhm

McGill University, Montreal

P.W.F. Fischer, BSc, PhD

Chief, Nutrition Research Division
Food Directorate, Health Protection Branch
Health Canada, Ottawa

W.C. Foong, BSc(Hons), PhD

Associate Professor
Division of Oral Biology, Faculty of Dentistry
Dalhousie University, Halifax

M.J. Friedland, MD, FRCPC

Department of Anaesthesia
Trillium Health Centre, Mississauga Site
Mississauga, Ontario

R.E. Grymonpre, BScPharm, PharmD

Associate Professor, Faculty of Pharmacy
University of Manitoba, Winnipeg

A. Guberman, MD, FRCPC

Professor, Neurology Division
University of Ottawa
The Ottawa Hospital, General Campus

D.A. Haas, DDS, PhD, FRCDC

Associate Professor
Department of Anaesthesia, Faculty of Dentistry
Department of Pharmacology, Faculty of Medicine
University of Toronto

B.G. Hardy, PharmD, FCSHP, FCCP

Coordinator—Clinical Programs, Department of Pharmacy
Sunnybrook Health Sciences Centre
Associate Professor, Faculty of Pharmacy
University of Toronto

R. Hossie, BScPhm, MScPhm, PhD

Bureau of Drug Surveillance
Therapeutic Products Programme
Health Canada, Ottawa

S. Ito, MD, ABCP

Division of Clinical Pharmacology
Department of Pediatrics
Hospital for Sick Children, Toronto

M. Jones, MD, FRCPC

Director, EEG Laboratory
Neurology Division
Vancouver General Hospital

S.H. Kennedy, MD, FRCPC

Head, Mood and Anxiety Division
Clarke Institute of Psychiatry, Toronto
Professor and Head, Mood Disorders Program
University of Toronto

S. Lovell, BScPhm

Department of Pharmacy
London Health Sciences Centre, University Campus
London, Ontario

A. Massicotte, BPharm, MSc

Drug Information Centre
The Ottawa Hospital, Civic Campus

I. MacKay, BSc(Hons), MSc

Acting Head, Special Access Programme
Therapeutic Products Programme
Health Canada, Ottawa

V.J.H. Marchessault, MD, FRCPC

Chairman, National Advisory Committee on Immunization
Department of Pediatrics
Children's Hospital of Eastern Ontario, Ottawa

CONTRIBUTORS/REVIEWERS (cont'd)

A.E. McCarthy, MD, FRCPC, DTM&H

Director, Tropical Medicine and International Health Clinic
The Ottawa Hospital, General Campus

R.S. McLachlan, MD, FRCPC

Epilepsy Unit
London Health Sciences Centre, University Campus
London, Ontario

M.J. McQueen, MB, ChB, PhD, FCACB, FRCPC

Director, Hamilton Regional Laboratory Medicine
Director, Lipid Research Clinic
Hamilton General Hospital Campus
Professor of Pathology
McMaster University, Hamilton, Ontario

D.G. Mills, BSc, PhD

Coordinator, Drug Information Services
Department of Pharmacy
London Health Sciences Centre, London, Ontario

S. Ottawa, BScPharm

Pharmacist
Mississauga, Ontario

C.J. Patterson, MD, FRCPC, FACP

Professor
Division of Geriatric Medicine
McMaster University, Hamilton, Ontario

R. Pless, MD, MSc

Head, Vaccine-associated Adverse
Events Surveillance Section
Division of Immunization
Laboratory Centre for Disease Control
Health Canada, Ottawa

N. Ramuscak, BScPhm

Clinical Pharmacist, Neurosurgery and Orthopaedics
Trillium Health Centre, Mississauga Site
Mississauga, Ontario

M.B.M. Sundaram, MD

Professor, Department of Neurology
University of Mississippi
Jackson, Mississippi USA

H. Sutcliffe, BScPharm

Acting Head, Adverse Drug Reaction Reporting Unit
Bureau of Drug Surveillance
Health Canada, Ottawa

G. Sweeney, MD

McMaster University, Hamilton, Ontario

M.P. Thirlwell, MD, FRCPC, FACP

Professor of Medicine and Oncology
McGill University, Montreal
Acting-Chief, Department of Oncology
Montreal General Hospital

D. Wong, BScPhm

Pharmacist
Scarborough, Ontario

G.B. Young, MD, FRCPC

Department of Clinical Neurological Sciences
University of Western Ontario
London Health Sciences Centre, Victoria Campus
London, Ontario

SUPPORTERS

The financial support of the following companies is gratefully acknowledged:

| | | |
|---|--|--|
| <p>Abbott Albert Pharma Alcon Allerex Allergan AltiMed Alza Amgen Apotex Ashbury Biologicals/Herbal Laboratories Astra Axcan Pharma Baxter Bayer Bayer Consumer BDH Bencard Berlex Canada Berna Products BioChem Vaccines Biomatrix Bioniche Block Drug Boehringer Ingelheim Bristol Bristol-Myers Squibb Canderm Pharma Cangene Carter Horner Chattem CIBA Vision Clintec Connaught Crystaal Dermik Laboratories Canada Dermtek Desbergers Dioptic Dispensapharm Dormer Draxis Health Duchesnay DuPont Pharma Endo Fabrigen Faulding Ferring Fournier Frosst Fujisawa Galderma</p> | <p>Genpharm Germiphene Glaxo Wellcome Glenwood Hoechst Marion Roussel Hoffmann-La Roche ICN Janssen-Ortho Johnson & Johnson • Merck Key Knoll Labcatal Leo Ligand Lilly Lundbeck Mallinckrodt May & Baker Pharma McNeil Consumer Products Mead Johnson Medican Pharma Medicis Medisan Pharmaceuticals Merck Sharp & Dohme Milex Nadeau Nestlé, Carnation NeXstar Novartis Consumer Health Novartis Nutrition Novartis Pharmaceuticals Novo Nordisk Novopharm Nu-Pharm Nycomed Odan Ophtapharma Organon Organon Teknika Parke-Davis Pfizer Pfizer Consumer Pharmaceutical Partners Pharmacia & Upjohn Pharmascience Procter & Gamble Procter & Gamble Pharmaceuticals Purdue Frederick R&D Laboratories Reed & Carnrick Rhodiapharm</p> | <p>Rhône-Poulenc Rorer RHO-Pharm RhoXalPharma Riva Rivex Ophthalmics Rivex Pharma Roberts Rougier Sabex Sanofi Schein Pharmaceutical Schering Searle Serono Servier Shepherd Sigma-Tau SmithKline Beecham SmithKline Beecham Consumer Healthcare Smith & Nephew Solvay Pharma SpectroPharm Dermatology Squibb Stanley Stiefel Sun Swiss Herbal Tanta Taro Technilab Therapex 3M Pharmaceuticals Trans CanaDerm Trianon UCB Pharma Warner-Lambert Consumer Healthcare Waymar Welcker-Lyster WestCan Westwood-Squibb Whitehall-Robins Wyeth-Ayerst Zeneca Zila</p> |
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GENERAL CONSIDERATIONS

In the *CPS* 34th edition (1999), the format of previous editions has been retained and the policy of making improvements has been continued.

Great care has been taken to ensure the accuracy and completeness of the information contained in the *CPS*. However, the editors and publishers are not responsible for errors or any consequences arising from the use of the information published herein.

Users are advised that the information provided in the *CPS* is not exhaustive. Other sources may contain additional necessary information for safe use of the product.

The *CPS* monographs in the **White Section** are based on information received from the manufacturers and the Therapeutic Products Programme, Health Canada. Included are those products and medical devices with a drug component available for use in Canada. Products registered under the Food and Drug Regulations, Division 10, which are offered to the public for self-medication, are not generally included.

The inclusion of a manufacturer's product monograph in the *CPS* does not imply that the editors or the *CPS* Editorial Advisory Panel accept, endorse or recommend these preparations as being clinically superior to similar products of any other firm. Individual products may differ in their constituents. In addition to therapeutic or drug components, products may contain nonmedicinal ingredients. Examples of nonmedicinal ingredients include diluents, lubricants, binders, buffers, antioxidants, preservatives, fillers, flavors, coloring agents and sweeteners.

Product monographs contain information on nonmedicinal ingredients. This information has been voluntarily submitted by the manufacturers and compiled by the editors. A statement may appear in the "Supplied" sections of the monographs indicating the presence or absence of a specific nonmedicinal ingredient in the product. The lack of a statement indicates no information was available to the editorial staff regarding a specific nonmedicinal ingredient. *CPS* users are urged to consult the product monograph of the product dispensed (see Clin-Info Section for further discussion on this topic).

All of the product monographs in the *CPS* are sent to the manufacturers every year for review. Monographs that have been revised extensively by the *CPS* editorial staff, the manufacturer and/or the *CPS* Editorial Advisory Panel are designated "Reviewed..." and the

year when this occurred. Products that have been newly introduced on the Canadian market are designated "New Product 1998".

In the monograph section, not including the general monographs, products are alphabetically listed by names that are registered trademarks of the company whose name, in full or in abbreviated form, immediately follows it. The appropriate designation ® or ™ appears beside the product name. *CPS* users are cautioned regarding the unauthorized use of any registered trade name.

The monographs present unbiased, factual information on drugs in a format useful to health care practitioners. For additional product information, readers are referred to the pertinent scientific and professional literature, to the descriptive literature of the company concerned, or to its professional personnel.

Changes to monographs contained in the *CPS* received by the publisher after established deadlines are not included in this edition.

The general monographs have been developed by the *CPS* editors and/or contributors and reviewed by the *CPS* Editorial Advisory Panel. Those included in this edition are listed on page 3. Readers should be aware that the text may contain information different from that approved by the Therapeutic Products Programme, Health Canada and that the pharmaceutical manufacturers' approval has not been requested.

The **Clin-Info Section** includes tables identifying alcohol, gluten, sulfites and tartrazine content of selected products. In addition, information on drug interactions, drug exposure during lactation and pregnancy, drugs and older individuals, drugs in dentistry, drugs to consider in patients with porphyria, antineoplastic drug therapy and clinical approaches on a variety of topics, as well as a directory of health organizations are included. The Clin-Info section contains information that is reviewed yearly by experts in their fields. For a complete listing of these topics, refer to Table of Contents on page L1.

Comments concerning the *CPS* 34th Edition (1999), its usefulness to the practitioners of the various health professions, and suggestions for the improvement of future editions are welcomed. Please use the Comment Card provided.

ERRATUM POLICY

Serious dosage errors, errors that threaten the patient's safety, or errors that could have other serious consequences will be considered for an erratum. In this event, a letter of correction or an appropriate insert will be sent to all known subscribers of the *CPS* as soon as possible.

Minor errors that do not have an impact on health care will be corrected in the next edition of the *CPS*. In some cases, such appropriate journals as the *Canadian Pharmaceutical Journal* and the *Canadian Medical Association Journal* will be used to convey changes that are not urgent or serious.

EDITORIAL POLICY

The *CPS* contains information about products intended for human use. Products are alphabetically listed by names that are the registered trademarks of the company whose name, in full or abbreviated form, immediately follows the trademark. General monographs are shown in the monograph section under the generic name or class.

The *CPS* is not intended to be exhaustive in terms of drug products available in Canada. The *CPS* editors compile, edit and distribute appropriate monographs which have been submitted by the manufacturer for inclusion in the book.

Users are advised that the information provided in the *CPS* is not exhaustive. Other sources may contain additional necessary information for safe use of the product.

Changes to monographs contained in the *CPS* received by the publisher after established deadlines are not included in this edition.

The *CPS* contains information on proprietary and nonproprietary products intended for human use.

The information provided in the *CPS* monographs is based on the Product Monograph prepared by the pharmaceutical manufacturers and accepted by the Therapeutic Products Programme, Health Canada. Product information as published in the *CPS* is a direct equivalent of the prescribing information contained and described in Sections 2.2 to 2.12 of the Drugs Directorate, Health Protection Branch Guidelines for Product Monographs (1989). Editorial changes are limited to those required for consistency of style, clarity and presentation.

Manufacturers' product monographs accepted by Therapeutic Products Programme and containing the same therapeutic ingredient(s) may differ in their indications, contraindications, warnings, precautions, adverse effects and dosing regimens. *CPS* users are encouraged to consult the product monograph of the product dispensed to ensure specific information.

Information published in various literature sources may be valuable to *CPS* users, and the *CPS* Editorial Advisory Panel may recommend additional information.

The general monographs are developed by the *CPS* editors and/or contributors and are based on information available from the originator's Product Monograph and independent literature sources. The *CPS* Editorial Advisory Panel reviews the monographs for accuracy and appropriateness with respect to current medical practice. Readers should be aware that the text may contain information different from that approved by the Therapeutic Products Programme, Health Canada and that the pharmaceutical manufacturers' approval has not been requested.

Prescribing information for products marketed before the publication of the Trade Information Letter, No. 302, June 6, 1968, is reviewed periodically in cooperation with the appropriate pharmaceutical manufacturer, Therapeutic Products Programme and the *CPS* Editorial Advisory Panel.

The Clin-Info Section contains selected information for health care professionals based on clinical practice and a review of the literature. The editors have collaborated with the contributors to compile this information. Although the information is not intended to be all inclusive, the editors, contributors and publisher have tried to ensure its accuracy at the time of publication. Readers should be aware that the text may contain information different from that approved by Therapeutic Products Programme and that the pharmaceutical manufacturers' approval has not been requested.

Drug therapy is constantly changing; consequently, it is the responsibility of the health care professional to seek additional and confirmatory information; to evaluate its appropriateness as it relates to the actual clinical situation; and to consider new developments.

What's new in *CPS* 1999

- Product News 1999
- Changes to the Clin-Info (Lilac) section
 - New sections added to Drugs in Dentistry, Antiepileptic Drug Therapy and Drug Exposure during Pregnancy
 - New format and complete reorganization of Drug Interactions table
 - Expanded sections on Clinical Laboratory Reference Values and Immunization Schedules
 - Completely revised information on Water Treatment Methods for Travellers
- New general monograph
 - Selective Serotonin Reuptake Inhibitors

PRODUCT NEWS 1999

Here is a quick look at what's new in the *CPS* 1999! New drugs (i.e., new chemical entities) with approved indications, previously available drugs with new indications, suppliers or dosage forms, new products (e.g., new generic products) and product name changes are listed. We hope this will help you to use the *CPS* more effectively than ever! Look for the product name in the *CPS* monographs section for more information.

CPS users are cautioned that listings may not be exhaustive although every effort has been made to include all applicable products. Only information pertaining to full product monographs is highlighted here.

| Brand Name | Generic Name/ Dosage Form | Manufacturer | Classification | Comments |
|-----------------------------------|---|-----------------------------|--|--|
| Accolate® | Zafirlukast 20 mg tablets | Zeneca | Leukotriene Receptor Antagonist | New drug—for the prophylaxis and chronic treatment of asthma in patients 12 years of age and older |
| Accuretic™ | Quinapril— Hydrochlorothiazide 10/12.5 mg and 20/12.5 mg tablets | Parke-Davis | ACE Inhibitor—Diuretic | New product—for the treatment of essential hypertension when combination therapy is appropriate |
| Acel-P™ | Acellular Pertussis Vaccine Adsorbed suspension for i.m. injection | Wyeth-Ayerst | Active Immunizing Agent | New product—for primary immunization (3 doses) of children 15 months-6 years of age against disease caused by <i>Bordetella pertussis</i> ; also for booster immunization as a fourth dose for children who previously received their primary immunization |
| Acyclovir Sodium for Injection | Acyclovir 500 mg and 1 g vials for i.v. infusion | Novopharm | Antiviral | New product |
| Acyclovir Sodium Injection | Acyclovir 25 mg/mL; 500 mg and 1 g vials for i.v. infusion | Faulding | Antiviral | New product |
| Advil® | Ibuprofen | Whitehall-Robins | Analgesic—Antipyretic | New dosage forms—200 mg gel caplets and 100 mg/5 mL children's suspension |
| Airomir™ | Salbutamol Sulfate 100 µg/actuation, 200 dose inhalation aerosol | 3M Pharmaceuticals | Bronchodilator— Beta ₂ -adrenergic Stimulant | New product—does not contain chlorofluorocarbons |
| Alesse™ 21 Alesse™ 28 | Levonorgestrel 100 µg— Ethinyl Estradiol 20 µg per tablet | Wyeth-Ayerst | Oral Contraceptive | New product |
| Alphagan™ | Brimonidine 0.2% ophthalmic solution | Allergan | Elevated Intraocular Pressure Therapy—Alpha Adrenergic Receptor Agonist | New drug—for control of intraocular pressure in open angle glaucoma or ocular hypertension |
| Amerge® | Naratriptan 1 and 2.5 mg tablets | Glaxo Wellcome | Migraine Therapy—5-HT ₁ Receptor Agonist | New drug—for the acute treatment of migraine attacks with or without aura |
| Antibiotic Cold Sore Ointment | Polymyxin B Compound | Novartis Consumer Health | Cold Sore Therapy | Name change—formerly Webber Antibiotic Cold Sore Ointment |
| Apo®-Acyclovir | Acyclovir 200, 400 and 800 mg tablets | Apotex | Antiviral | New product |
| Apo®-Cefaclor | Cefaclor 125, 250 and 375 mg/mL oral suspension | Apotex | Antibiotic | New dosage form—oral suspension |
| Apo®-Cromolyn | Cromolyn 2% nasal spray | Apotex | Seasonal Rhinitis Therapy | New product |
| Apo®-Cromolyn Sterules | Cromolyn 1% inhalation solution (2 mL) | Apotex | Prophylaxis of Symptoms of Bronchial Asthma | New product |
| Apo®-Domperidone | Domperidone 10 mg tablets | Apotex | Upper Gastrointestinal Motility Modifier | New product |
| Apo®-Etodolac | Etodolac 200 and 300 mg capsules | Apotex | Anti-inflammatory | New product |
| Apo®-Ketoconazole | Ketoconazole 200 mg tablets | Apotex | Antifungal | New product |

| Brand Name | Generic Name/ Dosage Form | Manufacturer | Classification | Comments |
|---|---|--|--|--|
| Apo®-Loxapine | Loxapine 5, 10, 25 and 50 mg tablets | Apotex | Antipsychotic | New product |
| Apo®-Moclobemide | Moclobemide 100 and 150 mg tablets | Apotex | Antidepressant | New product |
| Apo®-Oflox | Ofloxacin 200, 300 and 400 mg tablets | Apotex | Antibacterial | New product |
| Apo®-Terazosin | Terazosin 1, 2, 5 and 10 mg tablets | Apotex | Antihypertensive— Symptomatic Treatment of Benign Prostatic Hyperplasia | New product |
| Apo®-Ticlopidine | Ticlopidine 250 mg tablets | Apotex | Platelet Inhibitor | New product |
| Aspirin®, Coated Daily Low Dose | Enteric-coated ASA 81 mg | Bayer Consumer | Platelet Aggregation Inhibitor | New strength |
| Aspirin®, Coated Super Extra Strength | Enteric-coated ASA 650 mg | Bayer Consumer | Analgesic— Anti-inflammatory— Antipyretic | New strength |
| Astracaine® | Articaine 40 mg/mL— Epinephrine 1:200 000 | Astra | Local Anesthetic | New product—for infiltration and nerve block anesthesia in dentistry |
| Astracaine® Forte | Articaine 40 mg/mL— Epinephrine 1:100 000 | Astra | Local Anesthetic | New product—for infiltration and nerve block anesthesia in dentistry |
| Atracurium Besylate Injection | Atracurium 10 mg/mL vials for i.v. use | Faulding | Neuromuscular Blocking Agent | New product |
| Avapro™ | Irbesartan 75, 150 and 300 mg tablets | Bristol-Myers Squibb/ Sanofi Canada | Angiotensin II AT ₁ Receptor Blocker | New drug—for treatment of essential hypertension |
| Baycol® | Cerivastatin 0.2 and 0.3 mg tablets | Bayer | Lipid Metabolism Regulator | New drug—HMG-CoA reductase inhibitor |
| Beano® | Alpha-D-Galactosidase 150 GalU tablets and 150 GalU/5 drops | Block Drug | Alpha Galactosidase Enzyme | New product—to prevent digestive gas |
| Benadryl® Junior Strength Chewable Tablets | Diphenhydramine 12.5 mg chewable tablet | Warner-Lambert Consumer Healthcare | Antihistamine | New product |
| Benylin® DM 12 Hour | Dextromethorphan Polistirex 30 mg/5 mL controlled-release formula syrup | Warner-Lambert Consumer Healthcare | Antitussive | New product |
| Benylin® DM for Children 12 Hour | Dextromethorphan Polistirex 15 mg/5 mL controlled-release formula syrup | Warner-Lambert Consumer Healthcare | Antitussive | New product |
| Bleomycin Sulfate USP | Bleomycin 15 units/vial (lyophilized) for i.m., s.c., i.v., intra-articular, intrapleural or intraperitoneal use | Faulding | Antineoplastic | New product |
| Caltrate® Plus | Calcium Carbonate— Vitamin D—Magnesium— Zinc—Copper—Manganese tablets | Whitehall-Robins | Vitamin and Mineral Supplement | New product |
| Cerebyx® | Fosphenytoin Sodium 75 mg/mL for i.v. infusion or i.m. administration | Parke-Davis | Antiepileptic | New product—75 mg of fosphenytoin is equivalent to 50 mg/mL phenytoin sodium |
| Chronovera® | Verapamil 180 mg and 240 mg controlled-onset extended-release tablets | Searle | Antihypertensive— Antianginal | New product—formulation designed to initiate release of verapamil about 4-5 hours after ingestion and then a constant release over 12 hours |
| Cipro® | Ciprofloxacin 5 g/100 mL and 10 g/100 mL oral suspension; 2 mg/mL minibags of 100 and 200 mL | Bayer | Antibiotic | New dosage forms |
| Claritin® | Loratadine 10 mg rapid dissolve tongue tablets | Schering | Histamine H ₁ Receptor Antagonist | New dosage form |

| Brand Name | Generic Name/ Dosage Form | Manufacturer | Classification | Comments |
|---|---|--------------------------|---|--|
| Climara® | Estradiol-17β transdermal system | Berlex Canada | Estrogen | New product—once weekly application |
| Cytovene® | Ganciclovir 250 mg capsules and 500 mg vials | Roche | Antiviral | New indication—for the prevention of CMV disease in solid organ transplant recipients |
| Dalacin® C Phosphate Sterile Solution | Clindamycin 150 mg/mL injection | Pharmacia & Upjohn | Antibiotic | New indication—for treatment of <i>Pneumocystis carinii</i> pneumonia in patients with AIDS (with primaquine in patients who are intolerant to or fail to respond to conventional therapy) |
| Demadex® | Torsemide 5, 10, 20 and 100 mg tablets and 10 mg/mL ampuls | Roche | Diuretic | New supplier—formerly Boehringer Mannheim |
| Deproic® | Valproic acid 250 mg/5 mL syrup | Technilab | Anticonvulsant | New dosage form |
| Dexiron™ | Iron Dextran 50 mg/mL, 1 and 2 mL single dose vials | Genpharm | Iron Supplement | New product—for i.m. injection |
| Diane®-35 | Cyproterone 2 mg—Ethinyl Estradiol 0.035 mg tablets, 21 day pack | Berlex Canada | Antiandrogen—Estrogen Combination Hormone | New product—for treatment of androgen-dependent acne in females; also provides reliable contraception |
| Diclovec | Diclofenac 50 and 100 mg suppositories | Technilab | Nonsteroidal Anti-inflammatory Drug | New product |
| Dimetapp® Quick Dissolve | Brompheniramine 1 mg—Phenylpropanolamine 6.25 mg quick dissolve tablets | Whitehall-Robins | Antihistamine—Decongestant | New dosage form |
| Diovan® | Valsartan 80 mg and 160 mg capsules | Novartis Pharmaceuticals | Angiotensin II AT ₁ Receptor Blocker | New drug—for treatment of mild to moderate essential hypertension |
| Ditropan® | Oxybutynin 5 mg tablets and 5 mg/mL syrup | Alza | Antispasmodic | New distributor—formerly Procter & Gamble |
| Echinacea Angustifolia | Extract of Echinacea Angustifolia | Swiss Herbal | Herbal Medicine | New product—for relief of colds and minor flu symptoms |
| Echovist® | Galactose granules 3 g/vial and 20% solution, 13.5 mL/vial | Berlex Canada | Ultrasound Contrast Agent | New product—for ultrasound examination of the uterine cavity and fallopian tubes |
| Effexor® XR | Venlafaxine 37.5, 75 and 150 mg extended-release capsules | Wyeth-Ayerst | Antidepressant | New dosage form |
| Efudex® | 5-Fluorouracil 5% cream | ICN | Topical Antineoplastic | New supplier—formerly Roche |
| Elmiron™ | Pentosan Polysulfate Sodium 100 mg capsules | Alza | Interstitial Cystitis Treatment | New supplier—formerly Baker Cummins |
| Emadine® | Emedastine 0.05% ophthalmic solution | Alcon | Antiallergy | New drug—topical histamine H ₁ antagonist |
| EMLA® Cream | Lidocaine 25 mg—Prilocaine 25 mg per gram | Astra | Topical Anesthetic | New indication—for topical analgesia of leg ulcers in connection with mechanical cleansing/débridement |
| Epject® I.V. | Valproic Acid 100 mg/mL for i.v. injection; 5 mL single dose vials | Abbott | Anticonvulsant | New product |
| Euglucon® | Glyburide 2.5 mg and 5 mg tablets | Pharmascience | Hypoglycemic | New supplier—formerly Boehringer Mannheim |
| Evista™ | Raloxifene 60 mg tablets | Lilly | Selective Estrogen Receptor Modulator | New drug—for the prevention of osteoporosis in postmenopausal women |
| Ex-Lax® Chocolated Pieces, Sugar Coated Pills and Extra Strength Sugar Coated Pills | Sennosides 15 mg (25 mg in extra strength) | Novartis Consumer Health | Laxative | New product |

| Brand Name | Generic Name/ Dosage Form | Manufacturer | Classification | Comments |
|---------------------------------|--|---|---|---|
| Ex-Lax® Stool Softener | Docusate Sodium 100 mg caplets | Novartis Consumer Health | Laxative | New product |
| Famvir™ | Famciclovir 125, 250 and 500 mg tablets | SmithKline Beecham | Antiviral | New indication—to treat or suppress recurrent genital herpes in immunocompetent adults |
| Fexicam | Piroxicam 20 mg suppositories | Technilab | Nonsteroidal Anti-inflammatory Drug | New product |
| Flomax® | Tamsulosin 0.4 mg SR capsules | Boehringer Ingelheim | Alpha _{1A} -adrenoceptor Blocker | New drug—for treatment of benign prostatic hyperplasia |
| Flovent® | Fluticasone 50, 100, 250 or 500 µg blisters in a plastic inhaler device | Glaxo Wellcome | Corticosteroid | New dosage form |
| Fosamax® | Alendronate 5, 10 and 40 mg tablets | MSD | Bone Metabolism Regulator | New indications—for prevention of osteoporosis in post-menopausal women and for prevention of fractures in post-menopausal women treated for osteoporosis New strength—5 mg tablet |
| Fragmin® | Dalteparin Sodium for injection | Pharmacia & Upjohn | Anticoagulant— Antithrombotic | New indication—for unstable coronary artery disease i.e., unstable angina and non-Q-wave myocardial infarction |
| Fraxiparine™ | Nadroparin Calcium 9 500 IU anti-Xa/mL prefilled syringes | Sanofi | Anticoagulant—Low Molecular Weight Heparin | New drug—for prophylaxis of thromboembolism in general and orthopedic surgeries, treatment of deep vein thrombosis and prevention of clotting during hemodialysis |
| Gas-X® Gas-X® Extra Strength | Simethicone 80 and 125 mg tablets | Novartis Consumer Health | Antiflatulent | New product |
| Gemzar® | Gemcitabine 200 mg and 1 g vials for i.v. injection | Lilly | Antineoplastic | New indication—for treatment of nonresectable (Stage II or III) or metastatic (Stage IV) adenocarcinoma of the pancreas |
| Hydrasense® Nasal Care | Isotonic sterile 100% Natural-source Sea Water | Schering | Emollient | New product—for clearing nasal mucus caused by colds, allergies, sinusitis, rhinitis and dry air |
| Imodium® | Loperamide 2 mg caplets and 2 mg lingual tablets | Janssen-Ortho/McNeil Consumer Products | Antidiarrheal | New dosage form—lingual tablets |
| Imogam® Rabies Pasteurized | Rabies Immune Globulin 150 IU/mL, 2 and 10 mL vials for i.m. injection | Connaught | Immunoglobulin | New product—a heat treatment step has been added to the process |
| Kwellada-P™ | Permethrin 5% Lotion | R & C | Topical Scabicide | New product |
| Lescol® | Fluvastatin 20 and 40 mg capsules | Novartis Pharmaceuticals | Lipid Metabolism Regulator | New indication—to reduce the rate of progression of atherosclerosis in patients with coronary artery disease and mild to moderate elevations of cholesterol |
| Levaquin® | Levofloxacin 250 and 500 mg tablets and 5 and 25 mg/mL injections | Janssen-Ortho | Antibacterial | New drug—a quinolone for treatment of upper and lower respiratory tract, skin and urinary tract infections caused by susceptible organisms |
| Levotec | Levothyroxine 25, 50, 75, 100, 112, 125, 150, 175, 200 and 300 µg tablets | Technilab | Thyroid Supplement | New product |
| Levovist® | Galactose 99.9%—Palmitic Acid 0.1%; 200, 300 and 400 mg granules to be reconstituted for i.v. injection | Berlex Canada | Ultrasound Contrast Agent | New product—for Doppler sonographic blood flow imaging and B-mode contrast echocardiography |

| Brand Name | Generic Name/ Dosage Form | Manufacturer | Classification | Comments |
|---|--|--------------------------|--|--|
| Losec® | Omeprazole 10 and 20 mg tablets | Astra | Proton Pump Inhibitor | New indication—for treatment of NSAID-associated gastric and duodenal ulcers |
| Lovenox® | Enoxaparin 30 mg/0.3 mL prefilled syringe and 300 mg/3 mL multidose vial | Rhône-Poulenc Rorer | Antithrombotic | New indications—for prophylaxis of deep vein thrombosis in high risk abdominal, gynecological or urological surgeries and colorectal surgery; for treatment of pulmonary embolism; for treatment of unstable angina and non-Q-wave myocardial infarction New dosage form—multidose vial |
| Lupron Depot® 3.75 mg, 7.5 mg and 22.5 mg | Leuprolide 3.75 mg, 7.5 mg and 22.5 mg slow release injection | Abbott | Gonadotropin-releasing Hormone Analog | New product—now available as prefilled dual-chamber syringes as well as single dose vials with diluent |
| Maalox H2 Acid Controller™ | Famotidine 10 mg tablets | Novartis Consumer Health | Histamine H ₂ Receptor Antagonist | New product—for treatment and prevention of acid indigestion, heartburn, sour or upset stomach |
| Malarone™ | Atovaquone 250 mg— Proguanil 100 mg tablets | Glaxo Wellcome | Antimalarial | New product—for treatment of acute, uncomplicated <i>Plasmodium falciparum</i> malaria |
| Maxipime™ | Cefepime injection | Bristol-Myers Squibb | Antibiotic | New indication—in pediatric patients, for the treatment of the following infections when caused by susceptible organisms: lower respiratory tract, urinary tract, skin and skin structure; and as empiric therapy in febrile neutropenia |
| Mavik™ | Trandolapril 0.5, 1 and 2 mg tablets | Knoll | ACE Inhibitor | New indication—following acute MI in stable patients with left ventricular dysfunction, to improve survival and reduce hospitalizations for heart failure |
| Methylprednisolone Sodium Succinate for Injection USP | Methylprednisolone 500 mg and 1 g/vial (lyophilized powder) for i.v. or i.m. injection | Faulding | Glucocorticoid | New product—includes vial of bacteriostatic water for injection for reconstitution |
| Micanol® | Anthrakin 1% cream | Canderm Pharma | Psoriasis Treatment | New product |
| Micatin® | Miconazole 2% spray | McNeil Consumer Products | Topical Antifungal | New dosage form |
| Mirapex® | Pramipexole 0.25, 1 and 1.5 mg tablets | Boehringer Ingelheim | Antiparkinsonian | New drug—a non-ergot dopamine agonist for the treatment of Parkinson's disease |
| Mitomycin for Injection, USP | Mitomycin 5 and 20 mg/vial (lyophilized powder) for i.v. and intravesical use | Faulding | Antineoplastic | New product |
| Motrin® (Children's) | Ibuprofen 100 mg/5 mL suspension | McNeil Consumer Products | Analgesic—Antipyretic | New product |
| Neptazane® | Methazolamide 25 and 50 mg tablets | Wyeth-Ayerst | Carbonic Anhydrase Inhibitor | New supplier—formerly Storz |
| Nidagel™ | Metronidazole 0.75% vaginal gel | 3M Pharmaceuticals | Antibacterial | New dosing—once daily application, as well as b.i.d., now approved for bacterial vaginosis |
| Nitrolingual® Pumpspray | Nitroglycerin sublingual spray 0.4 mg per metered dose | Rhône-Poulenc Rorer | Antianginal | New product—does not contain chlorofluorocarbons |
| NovaSource™ Renal | Nutrition formula for oral or enteral use | Novartis Nutrition | Therapeutic Nutrient | New product—a calorically dense, moderate protein, low residue formula designed for dialysis patients |
| Novo-Cyproterone | Cyproterone 50 mg tablets | Novopharm | Antiandrogen | New product |