General

CPS contains information on proprietary and nonproprietary products intended for human use. Product monographs are organized alphabetically by brand names that are the registered trademarks of the company whose name, in full or abbreviated form, immediately follows the trademark. CPhA monographs are presented in the monograph section under the generic name or drug class. Titles of CPhA monographs are shaded in gray. The CPS Monograph section is not comprehensive of drug products available in Canada. Consult the Brand and Generic Index (green section) for a comprehensive list of products available in Canada. The editorial staff of CPhA compile and format monographs that have been submitted by the manufacturer for inclusion in the book. The inclusion of a manufacturer’s product monograph in CPS does not imply that the editors or the CPhA Editorial Advisory Committee accept, endorse or recommend these preparations as being clinically superior to similar products of any other manufacturer.

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

CPS 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 received by the publisher after the print deadline are available in CPS e-Suite. For more information, visit www.pharmacists.ca/cps.

Monograph Section

Product Monographs:

CPS provides Product Monographs prepared by pharmaceutical manufacturers and approved by the Therapeutic Products Directorate (TPD), Health Canada. Included are those products and medical devices with a drug component available for use in Canada. Product information as published in 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) and in the document Guidance for Industry: Product Monograph, Part I (Health Professional Information) and Part III (Consumer Information). Cross-references to Part II (Scientific Information) have been omitted since this section is not published in CPS. A revised product monograph template was implemented by Health Canada in October, 2003. Product monographs for new drugs and supplemental new drug submissions as well as drugs with notifiable changes approved since that date appear in the newer format. Older products remain in the previous format. Editorial changes are limited to those required for consistency of style, clarity and presentation.

Monographs approved by TPD for products containing the same therapeutic ingredient(s) may differ in their indications, contraindications, warnings, precautions, adverse effects, dosing regimens and constituents. CPS users are encouraged to consult the specific product monograph to ensure accurate information.

The product monographs contain listings of nonmedicinal ingredients. This information has been submitted voluntarily by the manufacturers and compiled by the editors. A statement may appear in the “Supplied” of “Dosage Forms, Composition and Packaging” sections indicating the presence or absence of a specific nonmedicinal ingredient in the product.

Lack of inclusion in this section 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). Contacting the manufacturer is recommended.

Some monographs contain boxed text indicating that the product has been approved under the Notice of Compliance with Conditions (NOC/c) policy of Health Canada. An NOC/c is a form of market approval granted to a product on the basis of promising evidence of clinical effectiveness following review of the submission by Health Canada. Products approved under this policy are intended for the treatment, prevention or diagnosis of a serious, life-threatening or severely debilitating illness. They have demonstrated promising benefit, are of high quality and possess an acceptable safety profile based on a benefit/risk assessment. In addition, they either respond to a serious unmet medical need in Canada or have demonstrated a significant improvement in the benefit/risk profile over existing therapies. Health Canada has provided access to this product on the condition that sponsors carry out additional clinical trials to verify the anticipated benefit within an agreed-upon time frame.

We request that manufacturers submit the most recent version of the product monograph for publication in print CPS. With the availability of CPS e-Suite, we are able to publish the most recent version of the monograph on a regular basis. The Date of Preparation and the Date of Revision (if applicable) are included for new or recently revised monographs. These dates will appear both in print CPS and CPS e-Suite, the latter being the most current publication.

Risk Factors for Drug Use During Pregnancy:

See Glossary at the end of the book for definitions on risk factors (A, B, C, D, X) for drug use during pregnancy.

CPhA Monographs:

CPhA monographs, titles shaded in gray and bearing the CPhA logo , are developed by the editorial staff of the Canadian Pharmacists Association. CPhA monographs are an important source of prescribing information that may not otherwise appear in CPS. They are based on the best available evidence and reviewed by expert physicians and pharmacists. Readers should be aware that the text may contain information different from that found in Health Canada-approved Product Monographs. The term “Uses Without Health Canada Approval” refers to indications not approved by Health Canada. The term “Use or Purpose” replaces “Indications” for natural health products as defined by Health Canada NHP database entry.

Clin-Info Section

The Clin-Info section provides quick reference clinical information and practice tools for healthcare professionals. This information is not intended to present a comprehensive review; the reader is therefore encouraged to seek additional and confirmatory information. Readers should be aware that the text may contain information different from that approved by the Therapeutic Products Directorate.

Errata

Despite our careful review process, should a major error occur it will be corrected immediately on www.e-cps.ca and posted on CPhA’s website: http://www.pharmacists.ca/errata. All errors will be corrected in the next print edition of CPS.