

Health Canada Endorsed Important Safety Information on metoclopramide



January 5, 2015

Dear Health Care Professional:

Subject: Association of metoclopramide with neurological adverse events (extrapyramidal symptoms) in the pediatric population

Sandoz Canada Inc., Apotex Inc., Omega Laboratories Limited and Pendopharm Division of Pharmascience Inc. in collaboration with Health Canada, would like to inform you of important new safety information regarding the risk of extrapyramidal symptoms in children taking the daily recommended dose of metoclopramide (0.5 mg/kg/day).

Metoclopramide is approved in Canada for the treatment of delayed gastric emptying and small bowel intubation.

- Extrapyramidal symptoms may occur in children receiving the daily recommended dose of metoclopramide that should not exceed 0.5 mg/kg.
- Metoclopramide is now contraindicated in children less than one (1) year of age as they appear to be at greater risk of extrapyramidal symptoms.
- Metoclopramide should not be used in children older than one (1) year unless the anticipated benefits clearly outweigh potential risks.

Health Canada completed a safety review on neurological adverse events in children receiving metoclopramide within the daily recommended dosage of 0.5mg/kg. The review concluded that a benefit-risk balance was negative in children under one (1) year of age due to safety concerns. Furthermore, it showed that metoclopramide should not be used in children older than one (1) year of age unless the anticipated benefits clearly outweigh potential risks.

The Canadian Product Monographs for metoclopramide drugs were revised recently to include the new contraindication and restrictions on the use of metoclopramide in children.

Managing marketed health product-related adverse reactions depends on health care professionals and consumers reporting them. Reporting rates determined on

the basis of spontaneously reported post-marketing adverse reactions are generally presumed to underestimate the risks associated with health product treatments. Any case of serious neurological adverse events or other serious or unexpected adverse reactions in patients receiving APO-Metoclop, Metoclopramide Hydrochloride Injection, Metoclopramide Omega or METONIA™ should be reported to Apotex Inc., Sandoz Canada Inc., Omega Laboratories Limited and Pendopharm Division of Pharmascience Inc., respectively or Health Canada.

Contact information for APO-Metoclopr

APOTEX INC.
150 Signet Drive, Weston, Ontario M9L 1T9
Phone: 1-800-667-4708

Contact information for Metoclopramide Hydrochloride Injection

Sandoz Canada Inc.
145, rue Jules-Léger, Boucherville, Québec J4B 7K8
Phone: +1 800 343 8839 (ext. 4636) (Drug Information/Pharmacovigilance)

Contact information for Metoclopramide Omega

Omega Laboratories Limited
11177 Hamon, Montreal, Quebec H3M 3E4
Phone: 1 800 363 0584 (ext. 392) (Medical Information)

Contact information for METONIA™

PENDOPHARM, Division of Pharmascience Inc.
6111, Royalmount Avenue, Suite 100, Montréal, Québec H4P 2T4
Phone: 1-888-550-6060 (Medical information)

To correct your mailing address or fax number, contact Sandoz Canada Inc.

You can report any suspected adverse reactions associated with the use of health products to Health Canada by:

- Calling toll-free at 1-866-234-2345; or
- Visiting MedEffect Canada's Web page on [Adverse Reaction Reporting](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax

For other health product inquiries related to this communication, contact Health Canada at:
Marketed Health Product Directorate
E-mail: mhpd_dpssc.public@hc-sc.gc.ca
Telephone: 613-954-6522
Fax: 613-952-7738

Sincerely,

Original signed by



Len Arsenault
Vice-President, Scientific Affairs
Sandoz Canada Inc.



Colin D'Cunha MBBS, MHSc, FRCPC
Director, Global Medical Affairs
Apotex Inc.



Marco Hamel
Director, Regulatory Affairs & Drug Development
Omega Laboratories Limited



Len Neirinck, Ph.D.
Vice-President and Chief Scientific Officer,
Scientific Affairs,
Pharmascience Inc.