

**Public Communication -
Health Canada Endorsed Important Safety Information on
metoclopramide**



January 5, 2015

Subject: Association of metoclopramide with abnormal involuntary movements (extrapyramidal symptoms) in children

Sandoz Canada Inc., Apotex Inc., Omega Laboratories Limited and Pendopharm Division of Pharmascience Inc. in consultation with Health Canada, would like to inform you of important new safety information concerning the potential risk of abnormal involuntary movements of the body called extrapyramidal symptoms that have been reported in children treated with metoclopramide at a recommended dose.

In Canada, metoclopramide is approved for the treatment of delayed stomach emptying and for medical procedures such as inserting a tube into the small bowel (called small bowel intubation).

- Abnormal involuntary movements called extrapyramidal symptoms may occur in children receiving the recommended dose of metoclopramide.
- Do not use metoclopramide in children less than one (1) year of age as they appear to be at higher risk of extrapyramidal symptoms.
- Do not use metoclopramide in children greater than one (1) year of age without talking to your doctor.

Health Canada completed a safety review on extrapyramidal symptoms in children receiving metoclopramide at the recommended daily dose. As a result of this review, Sandoz Canada Inc., Apotex Inc., Omega Laboratories Limited and Pendopharm Division of Pharmascience Inc. have worked with Health Canada to update the prescribing information for metoclopramide. Health care professionals have also been informed about this important new safety information.

Please contact your doctor if you notice abnormal involuntary movements or if you have any questions regarding your child's treatment with metoclopramide.

Managing marketed health product-related side effects depends on health care professionals and consumers reporting them. Any case of serious neurological adverse events or other serious or unexpected side effects in patients receiving APO-Metoclop, Metoclopramide Hydrochloride Injection, Metoclopramide Omega or METONIATM 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)

You can report any suspected side effect 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 Products Directorate
E-mail: mhpd_dpssc_public@hc-sc.gc.ca
Telephone: 613-954-6522
Fax: 613-952-7738

Sincerely,

Original signed by



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