Health Canada Endorsed Important Safety Information on Droperidol Injection USP

SANDOZ

August 25, 2010

Subject: **Association of Droperidol Injection USP with severe arrhythmia**

Dear Health Care Professional,

Sandoz Canada Inc., in consultation with Health Canada, would like to inform you of changes to the Canadian Product Monograph (CPM) for Droperidol Injection USP, the most important of which include the removal of certain indications, new contraindications, new warnings and dosage revisions. The reason for these changes is the previously observed risk of QT interval prolongation and severe arrhythmia.

- Droperidol Injection USP should only be used for the prevention and treatment of post-operative nausea and vomiting in patients for whom other treatments are ineffective or inappropriate.
- Droperidol Injection USP is no longer indicated for use in anesthesia for sedation or tranquilization, neuroleptanalgesia, or in the management of acute stages of Meniere's disease.
- Contraindications: Droperidol Injection USP is contraindicated in patients with known or suspected QT prolongation (i.e., QTc interval greater than 440 msec for males or 450 msec for females).
- New dosage:
  - Adults: 0.625 mg to 1.25 mg. Elderly: 0.625 mg.
  - Children over the age of 2 years and adolescents: 20 to 50 mcg/kg, up to a maximum of 1.25 mg.
- For intravenous use only.
- A new Boxed Warning highlights the risk of QT prolongation and measures to minimize this risk, including a recommendation for screening ECG and cardiac monitoring.

Cases of QT prolongation and/or torsades de pointes have been reported in patients receiving intravenous droperidol. Some cases have occurred in patients with no known risk factors for QT prolongation even at low doses. Some cases have been fatal.

Injectable droperidol should only be used in the hospital setting to allow for screening ECG. All patients should undergo a 12-lead ECG prior to administration of droperidol to detect prolonged QT interval. If there is a prolonged QT interval, droperidol should NOT be administered. Cardiac monitoring should start with treatment and be continued for 2 to 3 hours after completing treatment.

Extreme caution is needed when using droperidol in patients with risk factors for QT prolongation.

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 arrhythmia or other serious or unexpected adverse reactions in patients receiving Droperidol Injection USP should be reported to Sandoz Canada Inc. or Health Canada at the following addresses:

Sandoz Canada Inc.
145 Jules Léger
Boucherville, Quebec, Canada
J4B 7K8
Tel: 1-800-343-8839 ext. 4636
Fax: 1-888-243-6221

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program
    Health Canada
    Postal Locator 0701D
    Ottawa, Ontario K1A 0K9

The Reporting Forms, postage paid labels, and Guidelines can be found on the MedEffect™ Canada Web site in the Adverse Reaction Reporting section (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php). The Reporting Form is also in the Canadian Compendium of Pharmaceuticals and Specialties.

For other health product inquiries related to this communication, please contact Health Canada at:
Marketed Health Products Directorate (MHPD)
E-mail: MHPD_DPSC@hc-sc.gc.ca
Telephone: 613-954-6522
Fax: 613-952-7738

To change your mailing address or fax number, contact the Market Authorization Holder (Industry).

Sincerely yours,

original signed by

Leonard J. Arsenault
Vice-President, Scientific Affairs