

**Public Communication -
Health Canada Endorsed Important Safety Information on
domperidone maleate**



Subject: Domperidone maleate associated with serious abnormal heart rhythms and sudden death (cardiac arrest)

The manufacturers of domperidone in collaboration with Health Canada would like to inform you of additional safety information for domperidone concerning a small increased risk of abnormal heart rhythms and sudden death (cardiac arrest).

Domperidone is a medication used to treat symptoms of slowed stomach emptying and stomach inflammation. Domperidone is also used to prevent symptoms such as nausea and vomiting caused by some drugs used to treat Parkinson's disease.

This safety information is for patients taking domperidone for any condition. It is important for you to be aware of the following information:

- Some patients taking domperidone may have a small increased risk of serious abnormal heart rhythms or sudden cardiac arrest if they:
 - use doses higher than 30 mg a day;
 - are older than 60 years of age;
 - have certain conditions or take other drugs that may change the electrical activity of the heart (QT prolongation).
- You should not use domperidone if you:
 - have a known condition with abnormal electrical activity of your heart (called QT prolongation);
 - have low blood levels of potassium or magnesium;
 - have heart disease such as heart failure;
 - have moderate or severe liver disease;
 - take other drugs that may change the electrical activity of the heart or increase the amount of domperidone in your blood.
- If you experience any symptoms of abnormal heart rhythms such as heart palpitations, dizziness, fainting, or seizures while taking domperidone, you should stop taking domperidone and get immediate medical attention.

Changes to the electrical activity of the heart called QT prolongation can cause abnormal heart rhythms. These can be serious or life-threatening.

Domperidone should be used at the lowest effective dose for the shortest time possible. The maximum recommended dose is 30 mg a day (one 10 mg tablet three times a day). If you are already taking domperidone, contact your health care professional to find out if you are taking the correct dose for you.

Before starting treatment with domperidone, tell your doctor if you have or had any heart problems, low blood levels of potassium or magnesium, liver disease or if you are taking other medications, including medications without a prescription or natural health products.

Domperidone is also called domperidone maleate or:

Apo-domperidone	Domperidone-10
DOM-DOMPERIDONE	RAN-domperidone
Jamp-domperidone	Domperidone
Mar-domperidone	Ratio-domperidone
Mylan-domperidone	Teva-domperidone
PMS-DOMPERIDONE	

The manufacturers of all domperidone products are changing the prescribing information (called Product Monograph) for domperidone to include this safety information about serious abnormal heart rhythms and sudden cardiac arrest.

Managing marketed health product-related side effects depends on health care professionals and consumers reporting them. Any case of serious abnormal heart rhythms or sudden cardiac arrest, or other serious or unexpected side effects in patients receiving domperidone should be reported to the manufacturer (see the attached list) or Health Canada.

Apotex Incorporated Telephone: 1-800-667-4708 Telefax: 1-416-401-3819
Dominion Pharmacal Telephone: 1-888-550-6060 Telefax: 1-514-340-0164
Jamp Pharma Corporation Telephone: 1-866-399-9091 Telefax: 1-450-449-4325
Marcan Pharmaceuticals Inc. Telephone: (613) 228-2600 ext. 229; Fax: (613) 224-0444
Mylan Pharmaceuticals ULC Telephone: 1-800-575-1379 Telefax: 1-304-285-6409
Pharmascience Inc. Telephone: 1-888-550-6060 Telefax : 1-514-340-0164
Pro Doc Limitée Telephone: 1 800 361-8559 Telefax: 1 450 668-3585 or 1 888 977-6362
Ranbaxy Pharmaceuticals Inc. Telephone: 1-866-840-1340 Telefax: 1-905-602 4216
Sanis Health Inc. Telephone: 1-866-236-4076 Telefax: 1-905-689-1465
Sivem Pharmaceuticals ULC Telephone: 514-832-1286 Telefax: 514-832-1161
Teva Canada Limited and ratiopharm Inc.
1-800-268-4127 ext 1255005 (English), 1-877-777-9117 (French), Telefax: 1-416-335-4472

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 \(http://www.hc-sc.gc.ca/dhp-mps/medeff/repodeclaration/index-eng.php\)](http://www.hc-sc.gc.ca/dhp-mps/medeff/repodeclaration/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@hc-sc.gc.ca
Telephone: 613-954-6522
Fax: 613-952-7738

Yours sincerely,

Original signed by:



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