

Health Canada Endorsed Important Safety Information on
^NDarvon-N[®] : Recall and Withdrawal in Canada



November 25, 2010

Subject: Recall and Withdrawal of ^NDarvon-N[®] (dextropropoxyphene) in Canada

Dear Health Care Professional,

In collaboration with Health Canada, Paladin Labs Inc. has decided to voluntarily recall and withdraw all lots of ^NDarvon-N[®] (dextropropoxyphene, also known as propoxyphene) on the Canadian market and discontinue the sale of the product. This decision follows a United States Food and Drug Administration (FDA) request that all manufacturers of propoxyphene, an opioid pain reliever used to treat mild to moderate pain, withdraw their products from the U.S. market. The withdrawal is based on all available data, including data from a new study that evaluated the effects of increasing doses of dextropropoxyphene on the heart.¹

- Results of a new study show that, even at therapeutic doses, dextropropoxyphene can significantly prolong the PR interval, widen the QRS complex, prolong the QT interval and therefore increase the risk of serious abnormal heart rhythms.
- Elderly patients and those with renal insufficiency may be especially susceptible to the proarrhythmic effects of dextropropoxyphene.
- **Healthcare Professionals are asked to contact patients to whom they may have prescribed or dispensed this medication and instruct them to discontinue use and return unused medication to their point of purchase for disposal.**

Additionally, Healthcare Professionals should:

- Stop prescribing and dispensing ^NDarvon-N[®] to patients.
- Inform patients of the risks associated with ^NDarvon-N[®].
- Discuss with patients alternative pain management strategies other than ^NDarvon-N[®].
- Be aware of the possible risk of cardiac conduction abnormalities (prolonged QT, PR, and QRS intervals) in patients taking ^NDarvon-N[®] and assess patients for these events if they present with any signs or symptoms of arrhythmia.
- Report any side effects with ^NDarvon-N[®] to Paladin Labs Inc. or to the Canada Vigilance program. The contact information can be found in the box below.

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

1. Link to study information on Food and Drug Administration Website:
<http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM234330.pdf> .

post-marketing adverse reactions are generally presumed to underestimate the risks associated with health product treatments. Any case of serious heart rhythm abnormalities or other serious or unexpected adverse reactions in patients receiving ^NDarvon-N[®] should be reported to Paladin Labs Inc. or Health Canada.

Paladin Labs Inc.
6111 Royalmount Ave., Suite 102, Montreal, Quebec H4P 2T4
Tel.: 1-888-550-6060

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 0701E
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](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) 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

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).

Paladin Labs Inc. is committed to supplying you with high quality products and ensuring the highest level of patient care. Please do not hesitate to contact our Medical Services at 1-888-550-6060 if you need any additional information concerning this product recall and withdrawal.

Sincerely yours,

original signed by

Patrice Larose, B.Pharm., Ph.D.

Vice President, Scientific Affairs