PUBLIC COMMUNICATION
Health Canada Endorsed Important Safety Information on
RELISTOR (methylnaltrexone bromide)

Wyeth

2010-08-03

Subject: **Association of RELISTOR® (methylnaltrexone bromide) Subcutaneous Injection with gastrointestinal (GI) perforation**

Wyeth Canada (a Pfizer Company), in collaboration with Health Canada, is advising consumers of important updates to the prescribing information for RELISTOR.

RELISTOR is indicated for the treatment of opioid-induced constipation in patients with advanced illness who are receiving palliative care. When response to laxatives has been insufficient, RELISTOR should be used as an add-on therapy to induce a prompt bowel movement.

- If you have advanced illness and are being treated with RELISTOR, you may be at increased risk of gastrointestinal perforation especially in the presence of conditions that weaken the gastrointestinal wall (such as cancer, intestine cancer, gastro-intestinal ulcer, etc).

- Discontinue RELISTOR therapy and consult your physician if you develop severe, persistent, and/or worsening abdominal symptoms such as abdominal pain intensified by movement, nausea and vomiting or accompanied by fever and/or chills, as these could be symptoms of GI perforation.

Based on post-marketing experience, patients with advanced illness being treated with RELISTOR may be at increased risk of gastrointestinal perforation. To date, rare cases of gastrointestinal perforation have been reported in patients with complex confounding factors, such as associated medical conditions and medications taken in combination with RELISTOR, that may increase the risk of intestinal perforation. These include conditions such as cancer, GI malignancy, GI ulcer, and Ogilvie's syndrome and medications such as bevacizumab (AVASTIN), non-steroidal antiinflammatory drugs (NSAIDs) and steroids. This information has been communicated to the appropriate Canadian healthcare professionals.

The current Canadian prescribing information for RELISTOR (Product Monograph) can be accessed at www.wyeth.ca or at Health Canada's Drug Product Database at http://www.hc-sc.gc.ca/dhp-mps/prodpharma/databasdon/index-eng.php.

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 GI perforation or other serious or unexpected adverse reactions in patients receiving RELISTOR should be reported to Wyeth Canada or Health Canada at the following addresses:

Wyeth Canada (a Pfizer Company)
Medical Information and Pharmacovigilance
50 Minthorn Boulevard
Markham, Ontario L3T 7Y2
Tel : 1-800-268-1946, ext 4308
Fax : 1-800-734-5001

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

http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php

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
Tel: 613-954-6522
Fax: 613-952-7738

Sincerely,

original signed by

Bernard Prigent, MD, MBA.
Vice-President and Medical Director

References:
1. RELISTOR® (methylnaltrexone bromide) Subcutaneous Injection Product Monograph, Wyeth Canada. June 24, 2010