

Janssen-Ortho Inc.
Cobalt Pharmaceuticals Inc.
Novopharm Limited
Ranbaxy Pharmaceuticals Canada Inc.
ratiopharm inc.

PUBLIC COMMUNICATION
Health Canada Endorsed Important Safety Information on
Fentanyl Transdermal Systems (Patches)

January 7, 2009

SUBJECT: Important Changes to the Dosage Guidelines for Fentanyl Transdermal Systems (Patches)

The manufacturers of Fentanyl Transdermal Systems, in collaboration with Health Canada, are advising Canadians that important changes have been made to the dosage guidelines which are used to determine what dosage of Fentanyl Transdermal Systems is appropriate for each individual patient, and that this important safety information has been sent to all Canadian health care professionals and hospitals.

Fentanyl Transdermal Systems contain a high concentration of a potent and long-acting narcotic drug called fentanyl, which is administered through the skin by a patch system to treat persistent, moderate to severe chronic pain. Fentanyl Transdermal Systems (patches) are only intended for use in patients who require continuous around-the-clock pain relief with strong narcotic pain relievers for an extended period of time and who are already taking narcotic pain relievers at a total daily dose of at least 60 mg/day Morphine Equivalents.

The starting dosage of Fentanyl Transdermal Systems must be calculated using the new conversion tables, and must not be higher than that dose which is comparable to the total dose of the narcotic drug the patient is receiving before they are switched to the fentanyl patch.

Fentanyl is a very strong opioid narcotic pain medicine that can cause serious and life-threatening breathing problems if the dosage used is too high. Fentanyl Transdermal Systems should not be used in patients who are not already receiving opioid narcotic drugs, or for the treatment of postoperative pain.

Patients using a Fentanyl Transdermal Systems should seek emergency medical help immediately if they:

- have trouble breathing, or have slow or shallow breathing
- have a slow heartbeat
- have severe sleepiness
- have cold, clammy skin
- feel faint, dizzy, confused, or cannot think, walk, or talk normally
- have a seizure
- have hallucinations

Patients who are using Fentanyl Transdermal Systems without any of the above problems should not stop or decrease their dosage without discussion with their prescribing physician.

The letters to health care professionals and the notice to hospitals have been posted on the Health Canada website and can be accessed by means of the link below:

<http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/index-eng.php>

Manufacturers of all fentanyl transdermal patches are working with Health Canada to include this safety information in the Dosing and Administration section in all Canadian Product Monographs for Fentanyl Transdermal Systems:

Duragesic® (Fentanyl Transdermal Systems)

CO Fentanyl

Novo-Fentanyl

RAN-Fentanyl Transdermal Systems

ratio-FENTANYL Transdermal System

Managing 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 serious or unexpected adverse reactions in patients receiving Fentanyl Transdermal Systems should be reported to the manufacturers or Health Canada at the following addresses:

Janssen-Ortho Inc.

Drug Safety Department
19 Green Belt Drive
Toronto, Ontario M3C 1L9
Telephone: (800) 567-3331 or Fax: (866) 767-5865
E-mail: dsscan@joica.jnj.com

Cobalt Pharmaceuticals Inc.

6500 Kitimat Road
Mississauga, Ontario L5N 2B8
Telephone: 1-866-254-6111
Fax: 905-542-0478

Novopharm Limited

Pharmacovigilance and Drug Safety
30 Novopharm Court
Toronto, Ontario M1B 2K9
Telephone: 416-291-8888 ext. 5005
Fax: 416-335-4472
E-mail: PhV@Novopharm.com

Ranbaxy Pharmaceuticals Canada Inc.

2680 Matheson Blvd. East, Suite 200
Mississauga, Ontario L4W 0A5
Telephone: 1-866-840-1340
Fax: 905-602-4216

ratiopharm inc.

17800 Lapointe
Mirabel, Quebec J7J 1P3

Telephone: 1-800-337-2584
Fax: 1-800-313-7673
www.ratiopharm.ca
E-mail: drugsafety@ratiopharm.ca

Any suspected adverse reaction can also be reported to:

Canada Vigilance Program
Marketed Health Products Directorate
HEALTH CANADA

Address Locator: 0701C
Ottawa, Ontario, K1A 0K9
Tel: 613-957-0337 or Fax: 613-957-0335

To report an Adverse Reaction, consumers and health professionals may call toll free:

Tel: 866-234-2345

Fax: 866-678-6789

CanadaVigilance@hc-sc.gc.ca

The [AR Reporting Form](#) and the [AR Guidelines](#) can be found on the Health Canada web site or in *The Canadian Compendium of Pharmaceuticals and Specialties*.

http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/form/ar-ei_form_e.html

http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/guide/ar-ei_guide-ldir_e.html

For other inquiries related to this communication, please contact Health Canada at:

Marketed Health Products Directorate

E-mail: mhpd_dpsc@hc-sc.gc.ca

Tel: 613-954-6522

Fax: 613-952-7738

Authorized by:

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