

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

March 10, 2010

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

The manufacturers of Fentanyl Transdermal Systems, in collaboration with Health Canada, would like to inform Canadians of important **new changes made to the Dose Conversion Guidelines in the Product Monograph**. These guidelines are used to help determine what dosage of Fentanyl Transdermal Systems is appropriate for each individual patient.

Fentanyl Transdermal Systems are skin patches that contain a high concentration of fentanyl. Fentanyl is a very strong opioid narcotic used to help control chronic (long-lasting) 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 already are taking narcotic pain relievers at a total daily dose of at least 60 mg/day oral Morphine Equivalents.

- Health Care Professionals and hospitals have been informed of the new changes made to the Dose Conversion Guidelines. These new Guidelines will allow them to adjust doses appropriately.
- The dosage of Fentanyl Transdermal Systems must be calculated using the new conversion table, and must not be higher than the dose recommended.
- Patients using Fentanyl Transdermal Systems should not stop or change their dosage without first consulting with their doctor. This medicine should always be used exactly as prescribed.

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.

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

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 system)
TEVA-fentanyl
RAN-FENTANYL TRANSDERMAL SYSTEM
CO Fentanyl
Sandoz Fentanyl MTX Patch

DURAGESIC® MAT (fentanyl transdermal system)
ratio-FENTANYL Transdermal System
RAN-FENTANYL MATRIX PATCH
PMS-FENTANYL MTX

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
Fax: (866) 767-5865
E-mail: dsscan@joica.jnj.com

Cobalt Pharmaceuticals Inc.
6500 Kitimat Road
Mississauga, Ontario L5N 2B8
Telephone: (866) 254-6111
Fax: (905) 542-0478

Teva Canada 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@tevacanada.com

Ranbaxy Pharmaceuticals Canada Inc.
2680 Matheson Blvd. East, Suite 200
Mississauga, Ontario L4W 0A5
Telephone: (866) 840-1340
Fax: (905) 602-4216

ratiopharm inc.
17800 Lapointe
Mirabel, Québec J7J 1P3
Telephone: (800) 337-2584
Fax: (800) 313-7673
www.ratiopharm.ca
E-mail: drugsafety@ratiopharm.ca

Sandoz Canada Inc.
Pharmacovigilance General Contact
145 rue Jules-Léger
Boucherville, Québec J4B 7K8
Tel: (800) 343-8839 ext 4636
Fax: (450) 641-6408
Email: drugsafety.canada@sandoz.com

Pharmascience Inc.

Medical Information Dept.
6111 Royalmount Ave., Suite #100
Montreal, Quebec H4P 2T4
Telephone: (514) 344-0764 or (888) 550-6060
Fax: (514)340-0164
E-mail: adr@pharmascience.com

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_dpssc@hc-sc.gc.ca
Tel: 613-954-6522
Fax: 613-952-7738

Authorized by:

Janssen-Ortho Inc.
Cobalt Pharmaceuticals Inc.
Teva Canada Limited
Ranbaxy Pharmaceuticals Canada Inc.
ratiopharm inc.
Sandoz Canada Inc.
Pharmascience Inc.