

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

Health Canada Endorsed Important Safety Information on
Fentanyl Transdermal Systems

January 2, 2009

Dear Health Care Professional:

SUBJECT: Important Changes to the Dose Conversion Guidelines for Fentanyl Transdermal Systems

The manufacturers of Fentanyl Transdermal Systems (FTS), in collaboration with Health Canada wish to provide you with important information regarding changes to the **Dose Conversion Guidelines (Table 1.1)** and to the analgesic equivalency table: **Opioid Analgesics: Parenteral/Oral/Rectal Equianalgesic Potency Conversion (Table 1.2)** in the Dosage and Administration section of the Canadian Product Monographs for FTS. The **Dose Conversion Guidelines** are to be used to convert adult patients from their current oral or parenteral opioid therapy to the fentanyl transdermal patch. The analgesic equivalency table **Opioid Analgesics: Parenteral/Oral/Rectal Equianalgesic Potency Conversion**, may be used for adult patients taking opioids or doses not listed in Table 1.1, using the conversion methodology outlined for Table 1.1 with Table 1.2. The revised **Dose Conversion Guidelines** and **Opioid Analgesics: Parenteral/Oral/Rectal Equianalgesic Potency Conversion Table** are attached for your reference and should be retained for future consultation. Changes have been highlighted for ease of reference.

Serious or life-threatening hypoventilation can result if appropriate conversions are not used.

Based on clinical experience in patients with chronic pain:

- The conversion from IM/IV morphine to the fentanyl transdermal patch has been revised to reflect a conversion ratio of 1:2 and 1:3 of parenteral morphine to oral morphine.
- The conversion from IV hydromorphone to the fentanyl transdermal patch has been revised to reflect a conversion ratio of 1:2 of parenteral hydromorphone to oral hydromorphone.

The use of fentanyl transdermal systems in opioid-naïve patients and in patients with acute or postoperative pain is contraindicated.

In addition, the analgesic equivalency table 1.2 has been revised to remove the data equating 10 mg parenteral morphine to 60 mg oral morphine derived from single or intermittent dosing studies. Data referring to IM//IV oxycodone and to IM meperidine have been removed from both Tables 1.1 and 1.2 as the former drug is not marketed in Canada as an Injectable, and the latter drug causes CNS toxicity if used by the parenteral route chronically.

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

Duragesic® (fentanyl transdermal system)

CO Fentanyl

Novo-fentanyl

RAN-fentanyl transdermal system

ratio-FENTANYL Transdermal System

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

Please contact the appropriate manufacturer with any questions or concerns.

Authorized by:

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

References

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Ripamont, C, Pharmacology of Opioid Analgesia: Clinical Principles in Cancer Pain: Assessment and Management, edited by Bruera E and Portenoy RK. Cambridge University Press, 2003. p.124