



**PUBLIC ADVISORY**  
HEALTH CANADA ENDORSED IMPORTANT SAFETY INFORMATION  
DURAGESIC\* (*fentanyl transdermal system*)

**SUBJECT:** DURAGESIC\* (*fentanyl transdermal system*) Safety Information

TORONTO, September 16, 2005 – Janssen-Ortho Inc., in collaboration with Health Canada, wishes to highlight important safety information about the safe use of DURAGESIC. The Canadian Product Monograph for DURAGESIC has been revised to emphasize this safety information, and contains a section with Consumer Information to ensure that patients and their caregivers are aware of the guidelines for the safe use of DURAGESIC.

DURAGESIC contains a high concentration of a potent and long-acting narcotic agent called fentanyl, which is administered through the skin by a patch system to relieve pain.

Fentanyl, similar to other strong opioid pain medications, has demonstrated a risk of fatal overdose. The most serious effect of fentanyl overdose is hypoventilation (slowed breathing). Serious or life-threatening cases of hypoventilation (including deaths) have been reported in association with the use of DURAGESIC. Other symptoms of fentanyl overdose include difficult or shallow breathing, tiredness, extreme sleepiness or sedation; inability to think, talk or walk normally; and feeling faint, dizzy or confused. Patients and their caregivers should be aware of the signs and symptoms of fentanyl overdose, and should seek medical attention immediately if any of these symptoms are noted.

**DURAGESIC is used in adults for the management of persistent, moderate to severe chronic pain that cannot be managed by lesser means. It should not be used for short-term, intermittent or post-operative pain, or in patients who are not already using some form of strong opioid pain medication.**

**The use of DURAGESIC in children under 18 years of age is not recommended, as dosage requirements for the safe and effective use of DURAGESIC have not been established for children. There have been reports of deaths in children using DURAGESIC in Canada.**

The potential for serious adverse events may be increased in patients who:

- use DURAGESIC along with some other prescription medications that affect how fentanyl is broken down in the body. Patients should tell their doctors if they are taking any other prescription medications;

- use DURAGESIC in combination with alcohol and any other medications such as sleeping pills, muscle relaxants, antihistamines or any other over-the-counter medications that affect brain functions;
- have fever;
- are exposed to direct external heat sources. All patients who use DURAGESIC should be advised to avoid external heat sources such as heating pads, electric blankets, heated water beds, heat lamps, hot water bottles, saunas and hot whirlpool spa baths, intensive sun bathing, etc.;
- do not follow exactly the directions for safe use or the approved labeling.

The potential exists for misuse and abuse of DURAGESIC patches. There have been reports of deaths in Canada involving misuse and abuse. Consumers should be aware of the importance of safe storage and proper disposal instructions for DURAGESIC. Patients, family members and caregivers should protect DURAGESIC from theft or misuse in the work or home environment. The Canadian Product Monograph currently recommends to fold the patch such that the adhesive side sticks to itself and to flush it down the toilet immediately after removing it from the skin. Any unused patches should be disposed of in the same manner.

Janssen-Ortho Inc. has provided this information to physicians and pharmacists across Canada. This advisory and letters issued to physicians and pharmacists can be accessed at Health Canada's website at:

[http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/index\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/index_e.html)

This information is also available to <http://www.janssen-ortho.com>. For more information, patients should consult their health care professional. Patients should NOT discontinue their medication without consulting their physician or pharmacist first. If you or your caregiver have questions about DURAGESIC, please talk to your doctor or take the medication back to your pharmacy and speak to your pharmacist.

Janssen-Ortho Inc. is a research-based pharmaceutical company located in Toronto, Canada.

For further information on Janssen-Ortho Inc.: call Alexandra Gillespie, Janssen-Ortho Inc., (416) 449-9444. Or call the Janssen-Ortho Medical Information Department at 1-800-567-3331, from 9 a.m. to 5 p.m. Monday to Friday, EST.

Reporting rates determined on the basis of spontaneously reported post-marketing adverse events are generally presumed to underestimate the risks associated with drug treatments. The identification, characterization, and management of marketed health product-related adverse reactions are dependent on the active participation of health care professionals in adverse drug reaction reporting programmes. Any occurrences of serious and/or unexpected adverse reactions in patients receiving DURAGESIC should be reported to Janssen-Ortho Inc. or the Marketed Health Products Directorate at the following addresses:

Janssen-Ortho Inc.  
19 Green Belt Drive  
Toronto, Ontario  
M3C 1L9  
Or call toll-free at 1-800-567-3331  
Or email to [dsscan@joica.jnj.com](mailto:dsscan@joica.jnj.com)  
Or toll-free fax to 1-866-767-5865

For other inquiries at Health Canada, please refer to contact information:

**Marketed Health Products Directorate**

[MHPD\\_DPSC@hc-sc.gc.ca](mailto:MHPD_DPSC@hc-sc.gc.ca)

Tel: (613) 954-6522

Fax: (613) 952-7738

Any suspected adverse incident can also be reported to:

Canadian Adverse Drug Reaction Monitoring Program (CADRMP)

Marketed Health Products Directorate

HEALTH CANADA

Address Locator: 0701C

OTTAWA, Ontario, K1A 0K9

Local tel: 613-957-0337 or local fax: 613-957-0335

Toll-free tel: 1-866 234-2345 or toll-free fax: 1-866-678-6789

[cadrmp@hc-sc.gc.ca](mailto:cadrmp@hc-sc.gc.ca)

The ADR Reporting Form can be found in the Canadian *Compendium of Pharmaceuticals and Specialties* or on the TPD website along with the ADR Guidelines at:

[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/form/ar-ei_form_e.html)

[http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/guide/ar-ei\\_guide-ldir\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/guide/ar-ei_guide-ldir_e.html)