



JANSSEN-ORTHO

JANSSEN-ORTHO INC.

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February 15, 2008

Dear Doctor

On February 12, 2008, Janssen-Ortho Inc. initiated a Type II voluntary recall of DURAGESIC* (fentanyl transdermal system) 25 mcg/hr patches from wholesalers, pharmacies and patients. The recall is being conducted as a precaution in cooperation with Health Canada. The recalled patches all have expiration dates on or before December 2009, and all are manufactured by ALZA Corporation in the United States.

DURAGESIC 12.5 mcg/hr, DURAGESIC 50 mcg/hr, DURAGESIC 75 mcg/hr and DURAGESIC 100 mcg/hr strengths are **not** impacted by this recall.

Patients or caregivers should return the product to their pharmacy for safe disposal. Patches should not be handled directly. Consumers who have been using 25 mcg/hr strength of DURAGESIC fentanyl patches are advised to contact their treating physician for advice on a suitable alternative product for their medical condition.

The DURAGESIC 25 mcg/h patches being recalled may have a cut along one side of the drug reservoir within the patch. The result is possible release of fentanyl gel from the gel reservoir into the pouch in which the patch is packaged, exposing patients or caregivers directly to fentanyl gel. Fentanyl patches that are cut or damaged in any way should not be used. Exposure to fentanyl gel may lead to serious adverse events, including respiratory depression and possible overdose, which may be fatal. The prescribing information instructs anyone who comes in contact with fentanyl gel to thoroughly rinse exposed skin (or area) with large amounts of water only; **do not use soap or alcohol**. If the patient has opened the pouch containing an affected patch with cut edges, they should flush the patch down the toilet, using caution not to handle the patch directly. Patches with a cut edge that have leaked gel will not provide effective pain relief.

MANAGING POTENTIAL WITHDRAWAL – DURAGESIC should only be used in patients who have demonstrated opioid tolerance. It is important to note that in an opioid tolerant patient, abrupt opioid discontinuation may lead to withdrawal symptoms, which include sweating, sleeplessness, nausea, vomiting, diarrhea, anxiety, shivering and abdominal discomfort. Please refer to the Dosage and Administration and Decreased Dosing or Discontinuation sections of the DURAGESIC product monograph for additional information. Please assist the patient to manage their opioid therapy in some other manner to avoid any gaps in therapy and possible emergence of withdrawal symptoms.

We are committed to the integrity of our products and the health and safety of the patients who use them. For any other questions including suspected adverse reactions to this product, please contact Janssen-Ortho Medical Information at 1-800-567-3331, or Janssen-Ortho Customer Response Centre at 1-800-567-5667.

Sincerely,

Dr. Cathy Lau
Vice President, Regulatory Affairs and Quality Management
Janssen-Ortho Inc.