



URGENT Type II Voluntary Recall

DURAGESIC* 25 (fentanyl Transdermal system) 25 mcg/hr

Strength	DIN	JOI Product Number	UPC	Format (Unit)
25 mcg/hr	01937383	10651	062773 10651 8	5 x 25 mcg/hr

February 14, 2008

Dear Pharmacist,

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.

REASON FOR MARKET ACTION

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.

HEALTH ASSESSMENT

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 should contact their treating physician for advice on a suitable alternative product for their medical condition.

A comprehensive medical assessment to evaluate the potential impact of this occurrence has been completed. The approved product labeling provides clear warnings regarding the use of cut or damaged DURAGESIC patches and instructions regarding what actions should be taken if patients or caregivers are directly exposed to the fentanyl gel.

Fentanyl is a potent Schedule I opioid medication. Fentanyl patches that are cut or damaged in any way should not be used. 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.

ACTION REQUIRED BY PHARMACY

Please stop dispensing this product and quarantine the product.

Please accept returns from patients for DURAGESIC 25 mcg/hr. Further directions on how to handle product returns will follow in the next few business days. Janssen-Ortho will reimburse the pharmacy at its acquisition costs for product that remains in its inventory.

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,

Janssen-Ortho Inc.