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EXPANDED RECALL

Updated April 4, 2004

DURAGESIC®
(fentanyl transdermal system)

CII Patches[click here](#)**Control numbers****0327192****0327193****0327294****0327295****0330362**

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URGENT: EXPANDED PRODUCT RECALL

JANSSEN PHARMACEUTICA EXPANDS NATIONWIDE RECALL OF 75 MCG/HOUR DURAGESIC® (FENTANYL TRANSDERMAL SYSTEM) CII PATCHES

TITUSVILLE, NJ, April 5, 2004 - Janssen Pharmaceutica Products, L.P., is expanding its of DURAGESIC® (fentanyl transdermal system) CII 75 mcg/hour patches to include five manufacturing lots (**control numbers 0327192, 0327193, 0327294, 0327295, and 0330362**) other dosage strengths or control numbers are affected. Available by prescription only, DI patches contain a potent opiate medication. (For more detailed information, see www.Duragesic.com.)

The company recalled one lot of DURAGESIC 75 mcg/hour patches (control number 0327 February 2004 after determining that some patches in this lot might leak medication along Since then, patches with the same problem have been identified in one additional lot. As a precaution, the company is recalling four additional lots of 75 mcg/hour patches that were on the same manufacturing line during the same period.

DURAGESIC patches contain a strong opiate in the form of a gel. If the gel leaks from the patients can get either too much or too little medication. Exposure to too much medication if the gel leaks directly onto the skin and the body absorbs a higher than intended amount the medication is swallowed accidentally. This overexposure may cause potentially life-threatening complications. If the drug leaks out, there may not be enough medicine to achieve the desired and the patient may experience withdrawal symptoms.

The gel should not be touched if it leaks from a DURAGESIC patch. If a patient or caregiver unintended contact with the gel, they should immediately wash the affected area with large amounts of water only; soap should not be used. Patients should speak with their pharmacist or pharmacist for further instructions.

Anyone who has 75 mcg/hour DURAGESIC patches should examine the control number on the bottom flap of the outer carton or back of the foil pouch. Those who have patches with **control numbers 0327192, 0327193, 0327294, 0327295, and 0330362** must contact their physician or pharmacist immediately for specific instructions on returning patches from the recall and obtaining a new supply. Patients wearing other dosage strengths or DURAGESIC patches are not from the recalled lots can continue to wear them. Sudden discontinuation of DURAGESIC patches can cause serious health problems.

The affected lots were shipped only to distributors in the U.S. between mid-December 2003 and March 2004. Based on historic usage rates, the company estimates that the majority of patches from these lots already have been used. The company has consulted closely with the U.S. Food and Drug Administration on this expanded recall as well as the initial recall of DURAGESIC 75 mcg/hour patches in February 2004.

DURAGESIC patches are available in four dosage strengths - 25 mcg/hour, 50 mcg/hour, 75 mcg/hour and 100 mcg/hour. Only DURAGESIC 75 mcg/hour patches from lots with **control numbers 0327192, 0327193, 0327294, 0327295, and 0330362** are affected by this expanded recall. No other lots of the 75 mcg/hour patches are affected. No other dosage strengths are affected.

Patients, caregivers and health care professionals can further the understanding of adverse events and product defects relating to DURAGESIC by reporting all cases to Janssen Pharmaceutica Products, L.P. at the number listed below or to the FDA MedWatch Program by phone (1-800-338-8443), by fax (1-800-FDA-0178), by mail (using postage-paid form to MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20855).

Lane, Rockville, MD 20852-9787) or via www.accessdata.fda.gov/scripts/medwatch.

Janssen Pharmaceutica is committed to the integrity of its products and the health and safety of patients who use its products. For information on this product recall, please visit www.Duragesic.com or www.Janssen.com. The Web sites contain written material and photos of the pouch illustrating the control number. For those without Internet access or to report an adverse event, please call JANSSEN (1-800-526-7736).

Please see [full U.S. prescribing information](#), including boxed warning, at www.duragesic.com

Editors' Note: mcg per hour may also appear written as ug/hr

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