JANSSEN PHARMACEUTICA INC.

URGENT DRUG RECALL

April 2, 2004

Dear Healthcare Professional:

This is to inform you that Janssen Pharmaceutica Products, L.P., is expanding the recall of DURAGESIC® (fentanyl transdermal system) CII 75 mcg/hour patches to include five manufacturing lots (**control numbers 0327192, 0327193, 0327294, 0327295, and 0330362**). Patches from all other 75 mcg/hour and all 25, 50 and 100 mcg/hour patches are not part of this recall.

Some DURAGESIC patches from the recalled lots may leak medication due to improper sealing of one of their edges.

If medication leaks out of the patch, exposure to the medication could result in inadvertent ingestion or an increased transdermal absorption of the active opiate component fentanyl, leading to potentially life-threatening complications. In addition, leakage of medication could lead to inadequate dosing, resulting in treatment failure and/or opiate withdrawal.

Healthcare professionals, caregivers, or anyone who comes in contact with medication that may leak from DURAGESIC 75 mcg/hour patches from these lots (**control numbers 0327192, 0327193, 0327294, 0327295, and 0330362**) may be at risk of potentially life-threatening complications. Drug exposure among these persons could be more clinically significant because such individuals may not be opiate-tolerant. Anyone who comes in contact with the leaked medication is advised to rinse exposed skin thoroughly with water only; soap should not be used.

Please refer to the attached instructions on how to handle questions regarding the DURAGESIC 75 mcg/hour patches from recalled lots.
Guidance is provided on:

- Determining the affected lots of the product
- How to remove the patch
- How to handle used patches; and
- Obtaining a new supply of DURAGESIC 75 mcg/hour patches for the patient as soon as possible.

1125 TRENTON-HARBOURTON ROAD
POST OFFICE BOX 200
TITUSVILLE, NEW JERSEY 08560-0200
(609) 730-2000

us.janssen.com

Patients using DURAGESIC 25 mcg/hour, 50 mcg/hour, 100 mcg/hour, or DURAGESIC 75 mcg/hour patches that are not from the recalled lots (**control numbers 0327192, 0327193, 0327294, 0327295, and 0330362**) can continue to use them. Sudden discontinuation of DURAGESIC can cause loss of efficacy and/or opioid withdrawal.

Janssen Pharmaceutica Products, L.P. is committed to the integrity of its products and the health and safety of the patients who use them. For more information about this product recall, please visit www.DURAGESIC.com or www.Janssen.com. The Web sites contain written materials and photos of the outer carton and foil pouch illustrating the location of the control numbers. For those without Internet access, please call 1-800-JANSSEN (1-800-526-7736).

Report adverse events and product defects relating to DURAGESIC to Janssen Pharmaceutica Products, L.P. at 1-800-JANSSEN (1-800-526-7736), or to the FDA MedWatch Program by phone (1-800-FDA-1088), by fax (1-800-FDA-0178), by mail (using postage-paid form to MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787) or via www.accessdata.fda.gov/scripts/medwatch.

Please see attached Full Prescribing Information, including Boxed Warnings.

Sincerely,

Christine Côté, M.D.
Vice President, Medical Affairs
Janssen Pharmaceutica

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