

December 29, 2008

URGENT DRUG RECALL

PriCara®, Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc. is notifying all US Direct Accounts, Hospital and Retail Pharmacies of a voluntary recall of the product listed below. No other product marketed by PriCara® is impacted. This voluntary recall is being conducted in coordination with the U.S. Food and Drug Administration.

Product	NDC Number	Lot Number
Duragesic® 50 mcg/h (Fentanyl Transdermal System) CII Manufactured By: ALZA Corporation Mountain View, CA 94043	50458-034-05	0817239

REASON FOR MARKET ACTION

The lot of DURAGESIC® 50 mcg/h (Fentanyl Transdermal System) CII to be recalled may contain a small number of systems that have a cut along one side of the drug reservoir. The result is the possibility of gel being released from the gel reservoir into the pouch in which the patch is packaged that will allow patients or caregivers to be directly exposed to Fentanyl gel. Exposure to Fentanyl gel may lead to serious adverse events, including respiratory depression and possible overdose, which may be fatal.

HEALTH ASSESSMENT

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

Fentanyl is a potent Schedule II opioid medication. Fentanyl patches that are cut or damaged in any way should not be used. As described in the product labeling, anyone who comes in contact with Fentanyl gel should thoroughly wash exposed skin with large amounts of water only; do not use soap, alcohol, lotions, oils or other products to remove the medicine gel because they may increase the medicine's ability to go through the skin. Immediately dispose of affected patches with cut edges by flushing them down the toilet, using caution not to handle them directly. Patches with a cut edge that have leaked gel will not provide effective pain relief.

ACTION TO BE TAKEN:

1. Stop dispensing or distributing and quarantine the DURAGESIC® 50 mcg/h lot listed above.
2. Please carry out a physical count of your affected inventory of the indicated DURAGESIC® lot and record this data on the Business Reply Card that is included with this letter and return the reply to Stericycle, Inc. The Business Reply Card is postage paid.
3. **If you DO NOT have the recalled lot**, you must still complete the enclosed Business Reply Card and return it to Stericycle, Inc.
4. **If you DO have product to return**, upon receipt of the completed Business Reply Card, a Product Return Package, including: a DEA Form 222, Packing Slip and a prepaid UPS Authorized Return Service Shipping label will be forwarded to you by Stericycle on behalf of PriCara®. **A completed DEA Form 222 is required to process your return.**
5. Once you receive the Product Return Package, complete the accompanying Packing Slip. Enclose the completed Packing Slip along with the returned product. Please attach the prepaid UPS Authorized Return Service shipping label to the outside of the return carton and return to:

Stericycle, Inc.
Event# 1944
2670 Executive Drive, Suite A
Indianapolis, IN 46241

ADDITIONAL INFORMATION

- Credit for returned product will be issued to the direct wholesale and retail chain pharmacy accounts at the current list price. For assistance with product return, contact Stericycle at 1-888-202-5142.
- All other questions about this recall should be directed to The Customer Communications Center at 1-800-547-6446.