



PRICARA™ RECALLS 25 mcg/hr DURAGESIC® (fentanyl transdermal system) CII PAIN PATCHES

Other Strength Patches (12.5, 50, 75 and 100 mcg/hr) Not Affected

Raritan, NJ (February 12, 2008) - PriCara,™ Division of OrthoMcNeil-Janssen Pharmaceuticals, Inc. said today that all lots of 25 microgram/hour (mcg/hr) DURAGESIC® (fentanyl transdermal system) CII patches sold by PriCara in the United States and all 25 mcg/hr fentanyl patches sold by Sandoz Inc. in the United States are being voluntarily recalled as a precaution from wholesalers and pharmacies. The recalled patches all have expiration dates on or before December 2009, and all are manufactured by ALZA Corporation, an affiliate of PriCara. The recall is being conducted in cooperation with the U.S. Food and Drug Administration. All 25 mcg/hr fentanyl patches manufactured by ALZA and sold in Canada also are being recalled.

DURAGESIC 25 mcg/hr (fentanyl transdermal system) and Sandoz Inc. 25 mcg/hr fentanyl transdermal system 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. As per the approved product labeling for DURAGESIC, fentanyl is a potent Schedule II opioid medication. 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. Anyone who comes in contact with fentanyl gel should thoroughly rinse exposed skin with large amounts of water only; do not use soap. 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.

Anyone who has 25 mcg/hr DURAGESIC or Sandoz Inc. fentanyl patches should check the box or foil pouch for the expiration date to see if they have patches that are being recalled. The recalled patches all have expiration dates on or before December 2009. The cut edge in affected patches can be seen upon opening the sealed foil pouch that holds the patch. Affected patches should not be handled directly.

Anyone with 25 mcg/hr DURAGESIC patches being recalled should call 800-547-6446.

Anyone with 25 mcg/hr Sandoz Inc. patches being recalled should call 800-901-7236.

Patients using fentanyl patches who have medical questions should contact their health-care providers.

For more information, visit www.DURAGESIC.com.

DURAGESIC is used to manage persistent moderate to severe chronic pain that needs to be treated around the clock and which cannot be treated by: combination narcotic, short-acting, or non-narcotic pain treatment products. It should only be used by people who are receiving or have developed a tolerance to pain therapy with opioids. DURAGESIC should not be used if patients have pain that will go away in a few days, such as pain from surgery, medical or dental procedures, or short-lasting conditions. Any adverse reactions experienced with the use of fentanyl patches should be reported to the appropriate company using the telephone numbers above. DURAGESIC brand and other fentanyl patches are available by prescription only, through pharmacies, and should be used only under the supervision of a physician.

DUROGESIC™ patches sold in Europe, Latin America and Asia are not affected by this recall.