



January 6, 2009

Medication Recall Alert

MEDICATIONS: Duragesic® 50 mcg Patch, PriCara/Ortho-McNeil-Janssen
Fentanyl 50 mcg Patch, Sandoz Inc.

NDC: 50458-0034-05—Duragesic®, PriCara
00781-7112-55—Fentanyl, Sandoz Inc.

LOT: 0817239—Duragesic®, PriCara
0816851—Fentanyl, Sandoz Inc.

ISSUE: One lot of 50 mcg/hr DURAGESIC® (fentanyl transdermal system) CII patches sold by PriCara, and one lot of 50 mcg/hr fentanyl patches sold by Sandoz Inc. are being voluntarily recalled as a precaution from wholesalers and pharmacies

The following statement was released by PriCara on December 31, 2008:

“PriCara,® Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc., said today that one lot of 50 microgram/hour (mcg/hr) DURAGESIC® (fentanyl transdermal system) CII patches sold by PriCara in the United States and one lot of 50 mcg/hr fentanyl patches sold by Sandoz Inc. in the United States are being voluntarily recalled as a precaution from wholesalers and pharmacies. The recall is being conducted in cooperation with the U.S. Food and Drug Administration (FDA).

The company has identified a condition in the manufacturing equipment that has since been corrected. The condition resulted in a cut-system defect in a small number of affected patches in the lots being recalled. ALZA Corporation of Mountain View, CA, an affiliate of PriCara, manufactured the patches being recalled. DURAGESIC® 50 mcg/hr (fentanyl transdermal system) patches and Sandoz Inc. 50 mcg/hr fentanyl transdermal system patches being recalled may have a cut along one side of the drug reservoir. 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.

Anyone who has 50 mcg/hr DURAGESIC® or 50 mcg/hr Sandoz Inc. fentanyl patches should check the box or foil pouch to see if they have patches from the recalled lots. Cut patches should not be handled directly. Patients using fentanyl patches who have medical questions should contact their health-care providers.

DURAGESIC® 50 mcg/hr patches being recalled: Lot number 0817239.
Anyone with 50 mcg/hr DURAGESIC® patches from this lot should call 800-547-6446.

The Sandoz Inc. 50 mcg/hr patches being recalled: Lot number 0816851.
Anyone with 50 mcg/hr Sandoz Inc. patches from this lot should call 800- 901-7236.”