Patient Safety Alert

Veterans Health Administration Warning System
Published by VA Central Office

AL09-08 ADDENDUM March 10, 2009

This Alert amends and supersedes Patient Safety Alert AL09-08 originally issued on January 13, 2009. This addendum includes an additional recalled lot number and manufacturer not previously identified. All additions and changes in this Alert from the original have been underlined. No text has been deleted from the original Alert, except for the original action due date.

Item: Product Recall: Duragesic® 50 mcg/h (Fentanyl Transdermal System) CII (patch) National Drug code (NDC) 50458-034-05, Lot #0817239 **and Sandoz Inc. 50 mcg/hr patches Lot number 0816851**

Specific Incident: ALZA Corporation and Sandoz Inc. are recalling their Duragesic® 50 mcg/h Fentanyl transdermal patches. A small number of these systems may 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.

Actions: By close of business March 16, 2009, Pharmacy Chiefs will:

1) Assure that all remaining products with the affected lot numbers (#08 17239 and #0816851) at the facility are returned to McKesson, the pharmaceutical prime vendor for VA. The product should NOT be returned as instructed in the manufacturer/distributor's product recall documents.
2) Determine whether the affected lot number (refer to lot numbers provided above) was dispensed to any patient(s). If so, identify the patient(s) and contact the patient(s) providing instructions on how to obtain a new supply of medication and return the medication being recalled to the pharmacy so that your facility can double check them.
3) Call patients who may have received the affected product. Inform patients to "Contact your doctor immediately if you think you have absorbed too much Fentanyl or have become more sleepy than usual. Persons taking Fentanyl who become unconscious or too sleepy to wake up or have problems breathing need emergency help. Family members or caretakers should call 911."
4) If patients cannot be reached by telephone, follow-up with a letter. A sample letter can be found at: http://vaww.national.cmop.va.gov/PBM/Other%20Documents%20and%20Resources/Recall%20Patient%20Letter%20Template.doc. This template can be altered according to site-specific needs.
5) Report any adverse reactions experienced with the use of this medication to the VA ADERS program.

Additional Information: This product may be distributed by more then one vendor. Some of the names we are aware of are: Henry Schein, PriCara, Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc., Sandoz Inc. and McKesson.

Source: Manufacturers

Attachments:
1. Letter from Johnson & Johnson Health Care Systems Inc.
2. Letter from Henry Schein, Inc.
3. PriCara letter includes Sandoz Inc. recall lot number

Contact: Keith Trettin at the VA National Center for Patient Safety (734) 930-5848 and/or Vincent Calabrese at PBM (708)786-7862

ATTACHMENT 1

Johnson & Johnson
HEALTH CARE SYSTEMS INC.
Daniela Taylor
425 Hoes Lane
Post Office Box 6800
Piscataway, NJ 08855-6800
Phone: 732-562-7554
Fax: 732-562-2121
DTaylor@its.jnj.com

December 31, 2008

Mr. William R. Satterfield, III, Contracting Officer
Department of Veterans Affairs
National Acquisition Center
Federal Supply Schedule Service (049A1F1)
1st Avenue, just North of Cermak Road, Building 37
Hines, IL 60141

Subject: Voluntary Recall of Duragesic® 50 mcg/h (Fentanyl Transdermal System) CII

Reference: Ortho-McNeil-Janssen Pharmaceuticals, Inc., FSS Contract Number V797P-5813X

Dear Mr. Satterfield:

In accordance with clause AS1345 – RECALLS (MAY 1995) in the above referenced FSS contract, Johnson & Johnson Health Care Systems Inc. on behalf of Ortho-McNeil-Janssen Pharmaceuticals, Inc. hereby informs you of a voluntary recall for Duragesic® NDC 50458-034-05. The recall is specific to Lot Number 0817239. Recall notification is being distributed to all US Direct Accounts, Hospital and Retail Pharmacies. The reason for the recall and market action being taken is explained in Enclosure 1.

It is our understanding that this notification encompasses all of the information required per the terms of the AS1345 – RECALL clause. If there is additional information you require, please feel fee to contact me at (732) 562-7081.

Sincerely,

Daniela Taylor
Manager, Government Contracts

Enclosures:

1. Urgent Voluntary Recall Notice

ATTACHMENT 1

PriCara
Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc.

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.

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ATTACHMENT 2

December 31, 2008
Internal Distribution Letter-Manufacturer Letter Attached

URGENT: Drug Recall (Retail Level)

Manufacturing Firm:
Company ALZA Corporation

PRODUCT:

Product Code	Product Description	NDC / MFR Code	Lot #'s	Manufacturer Initial Ship Date
729-7452	Duragesic Patch 50mcg/H 5/Bx	50458-034-05	**0817239**	September 1, 2008

REASON:

This lot 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.

LEVEL:

This recall is to the Retail level.

CLASS:

This recall has not been classified. No additional notification will be given if this is classified as either a Class II or a Class III since the return information will be the same. The only update you will receive is if this is upgraded to a Class I.

ACTION:

Please examine your inventory to verify if you have any of the specified lot on hand. If so, immediately cease distribution/use of these products and remove them from your shelves. **If you have any of the affected lot, please contact our Customer Service Dept at 1-800-472-4346 to arrange for a controlled substance schedule II return.**

Once return has been authorized and proper 222 forms received, the products must be returned within 30 days, to the following address: **Henry Schein, Inc., 5315 W. 74th St, #138, Indianapolis, IN 46268.** Please clearly mark the carton **Recall Material Enclosed**. Your account will be credited accordingly for product, shipping and handling.

Only returns of the above noted recalled lot numbers purchased from Henry Schein, Inc. will be credited to your account. In order to expedite your credit, please send a copy of your invoice if available.

OTHER INFORMATION:

N/A

We apologize for any inconvenience and thank you for your immediate attention to this matter.

Sincerely,
Peter Schmidt
Recall Coordinator

ATTACHMENT 2

December 31, 2008

Internal Distribution Letter-Manufacturer Letter Attached

URGENT: Drug Recall (Retail Level) Response Form

Please note that only product codes and lot numbers affected by this recall should be returned to Henry Schein, Inc. Accounts will not be credited for non-affected product codes or lot numbers returned.

PLEASE SHIP AFFECTED PRODUCT TO:	FORWARD RESPONSES ONLY TO:
Henry Schein, Inc. 5315 W. 74th St #138 Indianapolis, IN 46268 **ATT: Customer Returns Department**	Regulatory Affairs Department (E-355) 135 Duryea Road Melville, NY 11747 **ATT: Regulatory-RR - Or - Fax Response To (631) 843-5557**

We have checked inventory and the following affected product has been found:

Product Code	Description	NDC / Mfr Product Code	Lot #'s	Manufacturer Initial Ship Date	Quantity
729-7452	Duragesic Patch 50mcg/H 5/Bx	50458-034-05	**0817239**	September 1, 2008	

_____ **WE DO NOT HAVE ANY OF THE AFFECTED ITEM.**

_____ _____ _____

Signature/Title Company Date

FOR HENRY SCHEIN, INC. INTERNAL USE ONLY		
TSM	**Lot Number (s)**	**Quantity**

ATTACHMENT 3

PRICARA® RECALLS 50 mcg/hr DURAGESIC® (fentanyl transdermal system) CII PAIN PATCHES

Other Strength Patches (12.5, 25, 75 and 100 mcg/hr) Not Affected

Raritan, NJ - 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.

As per the approved product labeling for DURAGESIC, fentanyl is a potent Schedule II opioid medication. Fentanyl patches that are cut or damaged in which may be fatal. 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 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.

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.

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.

For additional information, visit http://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. DURAGESIC patches sold in Canada are not affected by this recall. DUROGESIC™ patches sold in Europe, Latin America and Asia are not affected by this recall.