

Duragesic[®] (fentanyl transdermal system) Voluntary Recall

ONLY the 25 mcg/hr strength with an expiration date on or before December 2009 is affected.

BACKGROUND

Fentanyl, the primary active ingredient in both Duragesic and fentanyl transdermal patches sold by Sandoz, Inc., is a highly concentrated and potent Schedule II opioid agonist. This recall provides no new information or any changes to the safety of the active ingredient found in the Duragesic and Sandoz, Inc. patches. All narcotics can cause respiratory depression and can result in death in overdose situations.

At this time, the FDA has not issued a formal recall. This is a pre-emptive and voluntary recall.

NEW DEVELOPMENTS

On February 12, 2008, the PriCara[™] Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc. announced that all lots of 25 microgram/hour (mcg/hr) Duragesic (fentanyl transdermal system) commonly known as the fentanyl patch, 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 from wholesalers and pharmacies as a precaution. The fentanyl patches affected by this recall are all manufactured by ALZA Corporation, an affiliate of PriCara.

PriCara is voluntarily recalling these affected products due to a manufacturing containment and packaging issue, which is not related to the active ingredients of this drug. This recall pertains to **only** the 25 mcg/hr dosing strength (not to any other medication strengths) which shows an expiration date on or before December 2009. Both the brand and the specific generic formulation of this precise strength and expiration date grouping is affected, as they are manufactured by the same company.

This voluntary recall is limited to the patches sold by PriCara and Sandoz, Inc. There are other manufacturers of fentanyl transdermal patches that are not affected by this recall.

THE CONCERN

During the manufacturing packaging process of this medication, one side of the drug reservoir may have been inadvertently cut. This defect could result in the possibility of the medication (in gel form) being released from the gel reservoir into the pouch in which the patch is packaged. If a patch has been inadvertently cut, the open edge is evident upon opening the sealed foil patch and viewing the contents. To note, the defect rate based upon current information available is estimated to be less than 2 defects per million patches produced. Moreover, no deaths have been reported to be linked directly to this defect at this time.

At this time, the FDA has not issued a formal recall. This is a pre-emptive and voluntary recall.

For any additional patient information regarding this recall, visit www.duragesic.com/duragesic/recall_qa.html

Anyone who currently has the 25 mcg/hr Duragesic patches sold by PriCara should call 800.547.6446.

Anyone who currently has the 25 mcg/hr fentanyl transdermal patches sold by Sandoz, Inc. should call 800.901.7236.

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PMSI'S RECOMMENDATIONS/ ACTIONS TAKEN

1. Based on information currently available, and per FDA requirements, we recommend relying on the dispensing retail pharmacy to conduct the actual recall.
 - Each retail pharmacy should directly notify their affected customers, to whom they may have dispensed this medication.
 - Each retail pharmacy should remove the affected medication from their shelves to prevent any further dispensing of the recalled patches.
 - There are no actions for PMSI customers to take, nor cause for alarm.
2. We also recommend that no drug utilization review 'blocks' be placed upon the 25 mcg/hr strength patch or any other strength of fentanyl patch not affected by this recall, as:
 - The affected products will not be available to be dispensed to injured workers from the pharmacies until the manufacturing issues have been resolved.
 - There may be product available from the manufacturer that is not affected by this recall.
 - Generic patches are safely available from other manufacturers.
3. Be advised that you may receive approval requests for replacement prescriptions for the affected products.
4. At this time, PMSI's in-house mail order pharmacy is conducting a recall inspection of the identified medication, and will take the appropriate action to protect injured workers who may have received this medication through our mail order program.
5. This PMSI drug advisory reflects information currently released by the drug's manufacturer. If and when the FDA does issue an official recall, PMSI will publish an updated drug advisory communication that reflects this information.

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REFERENCES

www.duragesic.com/duragesic/recall_qa.html
Accessed February 14, 2008

Press Release, "PriCara™ Recalls 25 mcg/hr DURAGESIC® (fentanyl transdermal system) CII Pain Patches" URL: <http://www.prnewswire.com/cgi-bin/stories.pl?ACCT=104&STORY=/www/story/02-12-2008/0004754762&EDATE>