

Fentanyl pain patches are recalled

February 18 2008

The U.S. Food and Drug Administration announced the recall of Fentanyl transdermal system patches due to a potential safety hazard.

Actavis Inc. announced 14 lots of the patches sold nationwide might have a fold-over defect that could cause the patch to leak and expose patients or caregivers directly to the fentanyl gel. The FDA said Fentanyl is a potent opioid medication and exposure to the gel might 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, the company said.

Fentanyl transdermal patches are indicated for the management of persistent, moderate to severe chronic pain that requires continuous, around the clock opioid administration for an extended period of time and that cannot be managed by other means.

Complete recall information, including lot numbers, is available at <u>www.fda.gov/oc/po/firmrecalls/actavis02_08.html</u>

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