Generic Name:
Fentanyl transdermal patches
Trade Name:
Fentanyl Transdermal System 12
Company:
Alvogen/3M Drug Delivery Systems
Notes:

Alvogen is voluntarily recalling two lots (#180060 and #180073) of 12-mcg/h fentanyl transdermal patches because a small number of cartons were found to contain 50-mcg/h patches. The 50-mcg/h patches that were included in cartons labeled 12 mcg/h are individually labeled as 50 mcg/h. The transdermal system is manufactured by 3M Drug Delivery Systems, St. Paul, MN.

Application of a 50-mcg/h patch instead of a prescribed 12-mcg/h patch could result in serious, life-threatening, or fatal respiratory depression. Groups at potential increased risk could include first-time recipients of such patches, children, and older adults.

The product is indicated for management of pain in opioid-tolerant patients and is packaged in primary cartons of five individually wrapped and labeled pouches.

Alvogen is notifying its distributors and direct customers by certified letter and is arranging for return and replacement of all recalled products. Pharmacies should not dispense any product subject to this recall. Patients who have the product should immediately remove any patch currently in use, contact their health care provider, and return the unused product to point of purchase for replacement.

To date, Alvogen has not received any reports of adverse events related to this recall.

Medication Monitor Categories:
Alerts and Recalls