firstscript

Clinical Bulletin

April 24, 2019

Subject: Fentanyl Transdermal Patch Recall

Alvogen Inc. has issued a voluntary nationwide recall, to the consumer level, for two lots of Fentanyl Transdermal (TD) Patch due to product mislabeling. The product is indicated for the management of pain in opioid tolerant patients and is packaged in primary cartons of five individually wrapped and labeled pouches.

This recall involves two lots of Fentanyl TD patch labeled "12mcg/hr." A small number of cartons labeled "12mcg/hr" contained 50mcg/hr patches. The 50mcg/hr patches included in the cartons labeled "12mcg/hr" are individually labeled as 50mcg/hr.

Application of a 50 mcg/hr patch instead of a 12 mcg/hr 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 the elderly.

The affected lots of Fentanyl Transdermal Patches include:

- Lot 180060 – 12mcg/hr, expiration date: 05/2020
- Lot 180073 – 12mcg/hr, expiration date: 06/2020

Alvogen Inc. is notifying its distributors and direct customers by certified letter and is arranging for return and replacement of all recalled products. In addition, pharmacies have been requested not to dispense any product subject to this recall.

Patients that have products subject to this recall should immediately remove any patch currently in use and contact their health care provider. Patients with unused product should return them to the point of purchase for replacement.

The Impact

First Script is working to identify injured workers who may have been affected and will be following up as necessary. For more information, please contact your Account Manager or Account Pharmacist.

For additional recall information, visit: FDA Announcement - Fentanyl TD Patch Recall 042419.

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