Fentanyl Transdermal System 12mcg/h Patches – Alvogen Inc.

On April 21, 2019 the U.S. Food and Drug Administration (FDA) announced that Alvogen, Inc. voluntarily recalled two lots of Fentanyl Transdermal System 12mcg/h transdermal patches. This recall is due to a small number of cartons labeled 12mcg/hr Fentanyl Transdermal System patches that contained 50 mcg/hr patches.

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 the elderly.

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. The affected Fentanyl Transdermal System lots include:

Lot 180060 of Fentanyl Transdermal System, 12 mcg/h, expiration date 05/2020.
Lot 180073 of Fentanyl Transdermal System, 12 mcg/h, expiration date 06/2020.

The mislabeled product is packaged in a 12 mcg/h primary carton. These lots of Fentanyl Transdermal System were distributed Nationwide to the pharmacy level.

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

Questions regarding this recall should be directed to Alvogen Customer Complaints by calling 866-770-3024 or sending an e-mail to pharmacovigilance@alvogen.com Monday to Friday from 9:00 am to 5:00 pm EST. Consumers should contact their physician or health care provider if they have experienced any problems that may be related to taking or using this drug product.