

Immediate Release:

Recall of Two Lots of Generic Fentanyl

On April 19, 2019, the U.S. Food and Drug Administration (FDA) announced Alvogen's voluntary recall of two lots of Fentanyl Transdermal System 12 mcg/hr (transdermal patches) due to mislabeled product.

The product is packaged in cartons of five individually wrapped and labeled patches. A small number of cartons labeled as 12 mcg/hr contained 50 mcg/hr patches. The patches that were incorrectly included in the cartons are individually labeled as 50 mcg/hr. **Applying a 50 mcg/hr patch instead of a prescribed 12 mcg/hr patch could result in serious, life-threatening, or fatal respiratory depression.**

Fentanyl transdermal patches are used for pain in patients who are tolerant to opioid pain medications. Only product with the **specific NDC** and **lot numbers** listed below is being recalled.

Product	Lot or Batch Number	Expiration Date
NDC 47781-0423-47	Lot 180060	05/2020
	Lot 180073	06/2020

Patients with recalled product should immediately remove any patch currently in use and contact their health care professional. Patients should return any unused patches to the place of purchase and contact their health care provider if they have experienced any problems that may be due to using this product.

Questions regarding this recall should be directed to Alvogen Customer Complaints at 866-770-3024 or pharmacovigilance@alvogen.com, Monday through Friday, 9 am to 5 pm EST. Any adverse reactions experienced with the use of this product should be reported to the FDA's MedWatch Adverse Event Reporting program [online](#) or by calling 800-332-1088.

For additional information, please view the [FDA announcement](#).

References:

1. Alvogen Inc. Issues Voluntary Nationwide Recall of Fentanyl Transdermal System Due to Product Mislabeling. Company Announcement. Available at: <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/alvogen-inc-issues-voluntary-nationwide-recall-fentanyl-transdermal-system-due-product-mislabeling>. Updated April 19, 2019. Accessed April 23, 2019.