

Alvogen – Recall of fentanyl transdermal system

- On April 22, 2019, the <u>FDA announced</u> a voluntary, consumer-level recall of two lots of <u>Alvogen's fentanyl transdermal system</u> 12 mcg/h transdermal patches because a small number of cartons labeled 12 mcg/h fentanyl transdermal system patches contained 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 recalled lots were distributed nationwide to the pharmacy level.

Product Description	NDC#	Lot# (Expiration Date)
Fentanyl transdermal system, 12 mcg/h	47781-423-47	180060 (5/2020); 180073 (6/2020)

- Fentanyl transdermal system is indicated for the management of pain in opioid-tolerant patients, severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.
- Per Alvogen, 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.
- To date, Alvogen has not received any reports of adverse events related to this issue.
- Alvogen is notifying its distributors and direct customers by certified letter and is arranging for return
 and replacement of all recalled products. Pharmacies are requested not to dispense any product
 subject to this recall.
- 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 1-866-770-3024 or sending an e-mail to pharmacovigilance@alvogen.com.
- Patients should contact their healthcare provider if they have experienced any problems that may be related to taking or using fentanyl transdermal systems.



optumrx.com

OptumRx® specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum® company — a leading provider of integrated health services. Learn more at **optum.com**.

All Optum® trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews® is published by the OptumRx Clinical Services Department.

©2019 Optum, Inc. All rights reserved.