Humana

Pharmacy Solutions®

Drug recall notice for fentanyl transdermal system

To assist you in the care of your patients, Humana is alerting you to the recall of one lot of fentanyl transdermal system 25 mcg/h transdermal patches on Jan. 31, 2025.[1] We recommend you review your medical records and contact all patients for whom you have prescribed this medication to warn them of the recall.

Alvogen, Inc. is voluntarily recalling these products due to the possibility that some patches could be multi-stacked and adhered one on top of the other in a single pouch.

Fentanyl transdermal system is indicated for pain management in opioid-tolerant patients, requiring a prolonged treatment plan period that includes a daily opioid analgesic when other treatment options prove to be inadequate, according to the U.S. Food and Drug Administration (FDA).

"There is a possibility that the application of a multi-stacked 25 mcg/h patch could result in serious, life threatening, or fatal respiratory depression," the FDA said in a drug recall notice. "Groups at potential increased risk could include first-time recipients of such patches, children, and the elderly. To date, Alvogen has received one serious adverse event related to this recall."

Medications included in this recall

Product name	National Drug Code	Lot number	Expiration date
fentanyl transdermal system 25 mcg/h transdermal patches	47781-424-47	108319	April 2027
	47781-424-11	108319	April 2027

Information for providers:[1]

- We sent a letter to your Humana-covered patients with a claim for fentanyl transdermal system 25 mcg/h transdermal patches and asked them to contact their providers if their medication is included in the recall and if they have experienced problems that could be related to using these drug products.
- Providers with questions can contact:
    - Alvogen Customer Complaints by phone at 866-770-3024, Monday – Friday, 9 a.m. – 5 p.m., Eastern time, or by email at alvogensmb@continuumindia.com.
- Patients can report adverse reactions or quality problems experienced with the use of these products to the FDA's MedWatch Adverse Event Reporting Program online, by phone or by fax.
    - **Online:** Submit the report.
        - Select "Form FDA 3500 - Voluntary Reporting."
    - **Phone or fax:** Download the form.
        - Complete and submit "Form FDA 3500 - Voluntary Reporting" by phone at 800-FDA-1088 (332-1088) or by fax to 800-FDA-0178 (332-0178).

Reference

1. “Alvogen Issues Voluntary Nationwide Recall for One Lot of Fentanyl Transdermal System 25 mcg/h Due to a Defective Delivery System,” U.S. Food and Drug Administration, last accessed Feb. 10, 2025, https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/alvogen-issues-voluntary-nationwide-recall-one-lot-fentanyl-transdermal-system-25-mcgh-due-defective.