COMMUNICATION

COM-2025-009

3 FEBRUARY 2025

URGENT PLEASE REVIEW

Recall Notification

PharmPix Clinical Department

PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate the latest up-to-date drug recall information.

U.S. Food & Drug Administration Publication Date:

01/31/2025

Drug Information:

Product Description

Fentanyl Transdermal System 25 mcg/h transdermal patches

Lot Number

108319

Expiration Date

04/2027

Company:

Alvogen, Inc.

QUESTIONS

Contact Alvogen Customer Complaints by calling 866-770-3024 or sending an e-mail to alvogensmb@continuumindia.com Monday to Friday from 9:00 a.m. to 5:00 p.m. EST.

Fentanyl Transdermal System 25 mcg/h

It is for this reason that we are notifying you that on 01.31.2025 the U.S. Food and Drug Administration (FDA) published a drug recall for the following product(s): Fentanyl Transdermal System 25 mcg/h transdermal patch.

Pharmacy Required Action:

Identify if the product is in inventory and immediately stop using and dispensing it. The product should be returned to the place of purchase or as directed in the recall notification.

Advise patients that they should not discontinue using the medication without contacting their healthcare provider. Patients experiencing any problem while taking or using this product must contact their physician.

Reason for Recall:

Alvogen, Inc. is voluntarily recalling one lot of Fentanyl Transdermal System 25 mcg/h transdermal patches to the consumer level. The reason for the recall is that there is a potential that patches could be multi-stacked, adhered one on top of the other, in a single product pouch. This lot of Fentanyl Transdermal System was distributed nationwide to the pharmacy and patient level.

Risk Statement:

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. To date, Alvogen has received one serious adverse event related to this recall.

Remember you can report adverse events related to this or any other drug product at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:

Complete and submit the MedWatch Online Voluntary Reporting Form online.

Download FDA Form 3500 or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

Additional information can be found at: MedWatch: The FDA Safety Information and Adverse Event Reporting Program.

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252- ext.219. Our pharmacists will help you.

In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

PharmPix Drug Recall Communication Number COM-2025-009 February 2025

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REFERENCES:

1. U.S. Food and Drug Administration. (2025). *Alvogen Issues Voluntary Nationwide Recall for One Lot of Fentanyl Transdermal System 25 mcg/h Due to a Defective Delivery System*. Retrieved January 31, 2025 from https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/alvogen-issues-voluntary-nationwide-recall-one-lot-fentanyl-transdermal-system-25-mcgh-due-defective
2. MedWatch: The FDA Safety Information and Adverse Event Reporting Program- Available at: https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda

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