Alvogen Issues Voluntary Nationwide Recall for One Lot of Fentanyl Transdermal System 25 mcg/hr

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At Prime Therapeutics, we want to help you receive the best possible care. Visit our drug recall site for details: https://www.primetherapeutics.com/drugrecalls.

About this recall:
Alvogen is voluntarily recalling one lot of Fentanyl Transdermal System 25 mcg/hr patches (NDC: 47781-0424-47 and 47781-0424-11) to the consumer level. The recall is due to the potential for patches to be multi-stacked or adhered one on top of the other in a single product pouch.

For lot recalls, the lot/batch information and expiration date for the recalled product can be viewed by clicking on the link to the FDA Recall Notification found below.

The product is used for the management of severe and chronic pain in patients tolerant to opioid pain medications. It is used for patients that require an extended treatment period with a daily opioid pain medication; it is only used for those who do not have other options that will provide enough pain relief. It is packaged in cartons of five individually wrapped and labeled pouches.

What this means to you:
Application of a multi-stacked 25 mcg/hr patch could lead to serious, life threatening or fatal respiratory depression. Individuals at increased risk would potentially be first-time recipients of such patches, children and the elderly. To date, Alvogen has received one serious adverse event related to this recall.

Patients that have recalled product should immediately remove any patch currently in use and contact their health care professional. Patients with unused product should return it to the place of purchase for replacement. Consumers should contact their health care professional if they have experienced any problems that may be related to taking or using this drug product. Questions regarding this recall should be directed to Alvogen Customer Complaints by calling 866-770-3024 or sending an e-mail to alvogensmb@continuumindia.com, Monday to Friday from 9:00 am to 5:00 pm EST.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online.
- Regular Mail or Fax: Download form 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.

This recall is being conducted with the knowledge of the United States (U.S.) Food and Drug Administration.

For more information regarding this FDA Recall Notification, please refer to the FDA website: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/alvogen-issues-voluntary-nationwide-recall-one-lot-fentanyl-transdermal-system-25-mcgh-due-defective

FDA contact information for reporting adverse events/quality complaints can be reached online at https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home or by calling the FDA at 1-888-INFO-FDA (1-888-463-6332) and then selecting prompt #2.