

October 31, 2019

COM-2019-048

## **Recall:** Voluntary Nationwide Recall of Alprazolam Tablets

Dear provider of pharmaceutical services,

At PharmPix we are committed to the health and well-being of patients. It is for this reason that we inform you that on October 25, 2019, the U.S. Food and Drug Administration (FDA) issued a statement notifying that Mylan Pharmaceuticals Inc. is recalling one lot of Alprazolam 0.5mg Tablets C-IV due to potential contamination of a substance that could cause a type of infection.

The affected lot by the recall is detailed in following table.

Table 1: Affected Products of Alprazolam

NDC	Product & Pack	Lot	Expiration
0378-4003-05	Alprazolam Tablets, USP C-IV 0.5 mg, 500 Tabs	8082708	September 2020

## The Pharmacy must:

- 1. Identify if they have the product in inventory and immediately stop using and dispensing the product.
- 2. Contact all members that in the previous 90 days received the recalled medication and advised them to talk to their doctor. Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.
- **3.** Questions regarding this recall, refer to the contact information below:
  - a. **Retailers and Consumers -** contact Stericycle at 1-888-843-0255 for the documentation packet to return the product.
  - b. Consumers with questions regarding this recall can contact Mylan Customer Relations at 800.796.9526 or <u>customer.service@mylan.com</u>, Monday through Friday from 8 a.m. – 5 p.m. EST.





Remember that any adverse event related to this or any other pharmaceutical product can be reported to the FDA's MedWatch Adverse Event Reporting program:

- Online: <a href="http://www.fda.gov/medwatch/report.htm">www.fda.gov/medwatch/report.htm</a>
- Regular Mail or Fax: Download form <a href="http://www.fda.gov/MedWatch/getforms.htm">www.fda.gov/MedWatch/getforms.htm</a> 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

## For additional information visit:

<u>https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/mylan-pharmaceuticals-initiates-voluntary-nationwide-recall-one-lot-alprazolam-tablets-usp-c-iv-05</u>

## **Clinical Department**