COMMUNICATION

COM-2024-004

25 JANUARY 2024

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:

01/25/2024

Drug Information:

National Drug Code

24338-856-03

Product Description

Zenzedi™ (dextroamphetamine sulfate tablets, USP) 30mg

Batch Number

F230169A

Expiration Date

June 2025

Company:

Azurity Pharmaceuticals, Inc.

QUESTIONS

Call Inmar Intelligence at 1.877.804.2069 Monday – Friday from 9:00 a.m. to 5:00 p.m. EST / For medical questions call 1.800.461.7449 Monday – Friday from 9:00 a.m. to 5:00 p.m. EST.

Zenzedi™ Tablets

It is for this reason that we are notifying you that on 01.25.2024 the U.S. Food and Drug Administration (FDA) published a drug recall for the following product(s): Zenzedi™ (dextroamphetamine sulfate tablets, USP) 30mg.

Pharmacy Required Action:

Identify if the product is in inventory 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:

Azurity Pharmaceuticals, Inc., is voluntarily recalling one lot of Zenzedi™ (dextroamphetamine sulfate tablets, USP) 30mg, lot F230169A, to the consumer level. The recall was initiated due to mislabeled packaging. A bottle of Zenzedi™ 30mg tablets was found to contain tablets of carbinoxamine maleate, an antihistamine drug.

Should a patient receive carbinoxamine instead of Zenzedi™, the patient may experience undertreatment of their symptoms, drowsiness, sleepiness, central nervous (CNS) depression, increased eye pressure, enlarged prostate urinary obstruction, and thyroid disorder.

To date, Azurity has not received any reports of serious adverse events related 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 116. 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-2024-004 January 2024

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REFERENCES:

1. U.S. Food and Drug Administration. (2024). Azurity Pharmaceuticals, Inc. Issues Voluntary Nationwide Recall of Zenzedi™ (dextroamphetamine sulfate tablets, USP) 30 mg Due to a Mislabeled Package During Manufacturing. Retrieved January 25, 2024, from https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/azurity-pharmaceuticals-inc-issues-voluntary-nationwide-recall-zenzedir-dextroamphetamine-sulfate
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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