Azurity Issues Voluntary Nationwide Recall of Zenzedi® (dextroamphetamine sulfate) Tablets 30 mg Due to a Mislabeled Package

Date: 01/25/2024

About this recall:
Azurity is voluntarily recalling 1 lot of Zenzedi® (dextroamphetamine sulfate tablets) 30 mg to the consumer level. The product is being recalled due to a report from a pharmacist who opened a bottle of Zenzedi® 30 mg tablets and found tablets of carbinoxamine maleate, an antihistamine drug. The recalled drug is NDC # 24338-856-03 with lot # F230169A and expiration date June 2025.

Zenzedi® is a prescription medicine FDA-approved for (1) the treatment of narcolepsy and (2) as a treatment for attention deficit hyperactivity disorder (ADHD). The press release linked on the following page provides a description of the appearance of Zenzedi 30 mg tablets and a description of the appearance of carbinoxamine maleate tablets.

What this means to you:
Patients who take carbinoxamine instead of Zenzedi® will experience undertreatment of their symptoms, which may result in impairment and an increased risk of accidents or injury. Patients who consume carbinoxamine could experience side effects such as drowsiness, sleepiness, central nervous system depression, increased eye pressure, enlarged prostate leading to urinary obstruction, and thyroid disorders. For patients with ADHD and narcolepsy, the potential exists for accidents or injuries to occur due to the sedating effects of carbinoxamine. These accidents or injuries could be serious and result in disability or death in severe cases, especially if individuals engage in activities requiring significant focus and alertness, such as driving or operating heavy machinery. To date, Azurity has not received any reports of serious adverse events related to this recall.

Consumers that have product which is being recalled should stop using and return to the place of purchase. Consumers should contact their healthcare provider if they have experienced any problems that may be related to taking this recalled drug. An adverse event may also be reported to Azurity via email at aereports@azurity.com.

For more information regarding this recall, please refer to the following telephone numbers:

- For information on the recall process, call Inmar at 877-804-2069 (Monday to Friday, 9 am to 5 pm EST). - For medical information or to report a side effect, call 800-461-7449 (Monday to Friday, 9 am to 5 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 (US) 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/azurity-pharmaceuticals-inc-issues-voluntary-nationwide-recall-zenzedir-dextroamphetamine-sulfate

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.