Jan. 25, 2024

Azurity issues voluntary nationwide recall of Zenzedi (dextroamphetamine sulfate) tablets 30 mg due to a mislabeled package

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About this recall:

Azurity is voluntarily recalling one 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 number 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).

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 that is being recalled should stop using and return to the place of purchase. Consumers should contact their health care 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 phone numbers:

- For information on the recall process, call Inmar at **877.804.2069**, Monday–Friday, 9 a.m.–5 p.m. Eastern Standard Time (EST).
- For medical information or to report a side effect, call **800.461.7449**, Monday–Friday, 9 a.m.–5 p.m. EST.