Important Drug Recall Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC24-006-CG
February 8, 2024

FDA announced that, Woburn, Massachusetts, Azurity Pharmaceuticals, Inc. is voluntarily recalling one (1) lot (F230169A) of Zenzedi® CII (dextroamphetamine sulfate tablets, USP) 30 mg to the consumer level. The product is being recalled due to a report from a pharmacist in Nebraska who opened a bottle of Zenzedi® 30 mg tablets and found tablets of Carbinoxamine Maleate, an antihistamine drug. Upon learning of the incident, the manufacturer opened a product complaint and an investigation followed.

RECOMMENDATIONS

1. Azurity Pharmaceuticals, Inc. sent recall notification letters via overnight delivery to wholesale distributors on January 4, 2024, and arranged for the return of all recalled products at that wholesaler level. Consumers that have product which is being recalled should stop using and return to place of purchase. Azurity is working with wholesalers and retailers to arrange for the return and replacement of recalled product. Azurity has enlisted the services of Inmar Intelligence to facilitate the recall. Inmar is located at 3845 Grand Lakes Way, Grand Prairie, TX 75050. All returns from wholesalers and retailers must go to Inmar at this address.

2. For more information regarding this recall, please reference the following telephone numbers:
   a. For information regarding the recall process, call Inmar Intelligence at 877-804-2069 (Monday through Friday, 9AM-5PM EST).
   b. For medical or technical product information or to report a technical product complaint or adverse event please call 800-461-7449 (Monday through Friday, 9AM-5PM EST).

3. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product. An adverse event may also be reported to Azurity via email at aereports@azurity.com.

4. Review your inventory to identify existence of recalled products.

5. Expect patients to visit your pharmacy to deliver recalled products and prepare your pharmacy staff on how to handle the situation.

MC-Rx Pharmacy Services Department

T. (800) 377-1037
1267 Professional Pkwy, Gainesville, GA 30507
T. (787) 286-6032
Call Box 4908, Caguas, P.R. 00726
MC-Rx.com

FDA U.S. FOOD & DRUG ADMINISTRATION

Azurity Pharmaceuticals, Inc. Issues Voluntary Nationwide Recall of Zenzedi® (dextroamphetamine sulfate tablets, USP) 30 mg Due to a Mislabeled Package During Manufacturing

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SUMMARY:

Company Announcement Date:	January 24, 2024
FDA Publish Date:	January 25, 2024
Product Type:	Drugs
Reason for Announcement:	Mislabeled package
Company Name:	Azurity Pharmaceuticals, Inc.
Brand Name:	Zendedi
Product Description:	dextroamphetamine sulfate tablets, 30 mg

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COMPANY ANNOUNCEMENT

FOR IMMEDIATE RELEASE – January 24, 2024 – Woburn, Massachusetts, Azurity Pharmaceuticals, Inc. is voluntarily recalling one (1) lot (F230169A) of Zenzedi® CII (dextroamphetamine sulfate tablets, USP) 30 mg to the consumer level. The product is being recalled due to a report from a pharmacist in Nebraska who opened a bottle of Zenzedi® 30 mg tablets and found tablets of Carbinoxamine Maleate, an antihistamine drug. Upon learning of the incident, the manufacturer opened a product complaint and an investigation followed.

Patients who take carbinoxamine instead of Zenzedi® will experience undertreatment of their symptoms, which may result in functional impairment and an increased risk of accidents or injury. Patients who unknowingly consume carbinoxamine could experience adverse events which include, but are not limited to, drowsiness, sleepiness, central nervous system (CNS) depression, increased eye pressure, enlarged prostate urinary obstruction, and thyroid disorder. For patients with Attention Deficit Hyperactivity Disorder (ADHD) and Narcolepsy (sleep disorder) there is a reasonable probability that accidents or injuries that occur due to the sedating effects of carbinoxamine, could lead to ongoing disability or death in severe cases, particularly if individuals who use it (unaware that they have not received Zenzedi®) engage in activities requiring significant focus and alertness (e.g., driving, operating heavy machinery).

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To date, Azurity has not received any reports of serious adverse events related to this recall.

Zenzedi® is a prescription medicine for the treatment of Narcolepsy. Zenzedi® is also indicated as a treatment for attention deficit hyperactivity disorder (ADHD). Zenzedi® is marketed under Arbor Pharmaceuticals, LLC brand. Arbor Pharmaceuticals, LLC is a subsidiary of Azurity Pharmaceuticals, Inc. For additional Zenzedi® safety information, please visit www.azurity.comExternal Link Disclaimer.

Zenzedi® 30 mg tablets can be identified by light yellow hexagonal tablet debossed with "30" on one side and "MIA" on the other side and distributed in a white bottle with black writing and "30 mg" highlighted yellow. Whereas the description of the suspect tablets (Carbinoxamine Maleate Tablets USP, 4 mg), which was provided by the reporting pharmacist, was white round tablets with imprints of "GL" on one side and "211" on the other side. Product was distributed nationwide through pharmacies.

Product	NDC No.	Lot No.	Exp. Date	Ship Dates to Wholesalers
Zenzedi® (dextroamphetamine sulfate tablets, USP) 30 mg	24338-856-03	F230169A	2025-06	08/23/2023 – 11/29/2023

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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:** www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax:** Download form www.fda.gov/MedWatch/getforms.htm 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

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