

Azurity – Recall of Zenzedi[®] (dextroamphetamine)

- On January 24, 2024, <u>Azurity announced</u> a consumer level recall of one lot of <u>Zenzedi</u> (<u>dextroamphetamine</u>) 30 mg tablets because a bottle labeled as Zenzedi contained <u>carbinoxamine</u> tablets.
- This recalled lot was distributed nationwide through pharmacies:

Product Description	NDC number	Lot number (Exp Date)
Zenzedi (dextroamphetamine sulfate) 30 mg tablets	24338-856-03	F230169A (6/2025)

- Zenzedi is indicated for the treatment of narcolepsy and attention deficit disorder with hyperactivity (ADHD).
- 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 depression, increased eye pressure, enlarged prostate urinary obstruction, and thyroid disorder.
- For patients with ADHD and narcolepsy 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 (eg, driving, operating heavy machinery).
- To date, Azurity has not received any reports of adverse events related to this recall.
- Anyone with the affected products on hand should discontinue use, stop distribution and quarantine product immediately. Patients should contact their healthcare provider if they have experienced any problems that may be related to using the recalled products.
- Consumers may contact Azurity at **1-800-461-7449** for more information.



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