

*The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.*

Zydus Pharmaceuticals (USA) Inc. is recalling Lot No. E408618 of Mirabegron Extended-Release Tablets 25 mg.

The recall is based on an Out of Specification (OOS) result for N-Nitroso Mirabegron impurity detected in the product at the 8-month interval, during long-term stability condition testing. The presence of this impurity at levels exceeding acceptable limits may pose a possible increased risk of cancer with long-term exposure.

The product was shipped to our customers from May 2025 to August 2025.

PRODUCT: Mirabegron Extended-Release Tablets 25 mg, 30's Count Bottle Pack

NDC NUMBER: 70710-1159-3

LOT NUMBER: E408618

EXPIRATION DATE: 11/2026

DISTRIBUTION DATES: 05/30/2025 - 08/28/2025