

*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.*

This is to inform you that Glenmark is initiating a Market Withdrawal at the Retail level involving Ondansetron Orally Disintegrating Tablets USP 4 mg. Glenmark is initiating a market withdrawal at the Retail level as abundance of caution due to market complaint received for blisters not fully sealed and tablets falling out.

Glenmark received two (2) market complaints for unsealed blisters. Glenmark conducted the investigation and identified:

- Visual inspection performed for the reserve samples of complaint batch # 19251311 and other batches of Ondansetron Orally Disintegrating Tablets USP 4, concluded that no observations were noted similar to the nature of the complaint sample.
- The root cause was identified as the portion of Heat Seal Lacquer (HSL) found missing from the printed lidding foil supplied by the lidding foil supplier.
- The root cause is specific to one batch of lidding foil roll, which was only used for the packing of the complaint batch # 19251311.

Since the root cause is identified and specific to the complaint batch # 19251311, as an abundance of caution, Glenmark is initiating a market withdrawal of Ondansetron Orally Disintegrating Tablets USP 4 mg, batch # 19251311.

Health hazard assessment concluded that the product quality complaint of unsealed blister packs for Ondansetron orally disintegrating tablets is unlikely to have an impact on patient health and safety.

PRODUCT: Ondansetron Orally Disintegrating Tablets USP 4 mg, 3x10 Blisters

NDC NUMBER: 68462-157-13

LOT NUMBER: 19251311

EXPIRATION DATE: April 2027