

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 recall at the Retail level involving Theophylline Extended-Release Tablets 600 mg (100's Tablets).

The recall to the retail level of the below-identified Theophylline Extended-Release Tablets 600 mg batches have been initiated due to out-of-specification (OOS) results reported for the Dissolution (By UV) test for batch # 19242899 at 6 Months long-term (25°C/60% RH), batch # 19231955 at 18 months long-term (25°C/60% RH), and batch # 19234148 (Expiry: 09/2025), and 19242881 (Expiry: 06/2026) for reserve samples during impact evaluation testing. To date, Glenmark has not received any reports of adverse events related to this recall. It is not expected that the OOS results observed will cause serum theophylline levels to exceed the therapeutic range. Adverse effects associated with theophylline are generally mild at this level and mainly consist of transient effects such as nausea, vomiting, headache, and insomnia, which are similar to the effects reported with theophylline without OOS. Therefore, the potential risk associated with the observed OOS result is low.

Sr. No.	NDC Code	Batch Number	Pack Size	Expiry Date
1	68462-356-01	19234121	100's Tablets in Container	September 2025
2	68462-356-01	19234148	100's Tablets in Container	September 2025
3	68462-356-01	19242881	100's Tablets in Container	June 2026
4	68462-356-01	19242899	100's Tablets in Container	June 2026