

*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.*

Glenmark has initiated a recall of Indomethacin Capsules USP 25mg due to Market complaint was received from Customer Service Representative of Amerisource Bergen on behalf of Westwood Pharmacy Staff for the product Indomethacin Capsules USP 25mg, Batch # 19231903 (PQC no. CH-2023015651-00), stating that “The product was labelled as Naproxen Tablets USP 250 mg, but it actually contained Indomethacin Capsules USP 25 mg, and it was placed in an original manufacturer's bottle”.

On review of complaint sample photograph it was observed complaint bottle was labeled with “Naproxen Tablets, USP 250mg” and product inside the bottle pack was “Indomethacin Capsule 25mg”. The batch details and 2D code details were of Indomethacin Capsule 25mg.

Preliminary investigation reveals that, batch was manufactured as per the instructions mentioned in the batch production record without any deviation and no evidences were observed that could lead to label mix up at the drug product manufacturing site.

Reported complaint is an isolated event and as of now only one complaint for one bottle pack is received. Investigation was extended to the label supplier Barcom Industries Limited. Based on the initial assessment of the processes followed at the vendor’s end, it can be inferred that the above mix up with a stray label of “Naproxen Tablet” within the roll of “Indomethacin Capsule” had happened at the vendor’s end, however the extent of such mix up within a roll is very limited.

The lot number of label used in the impacted batch was also used in four (4) other batches of Indomethacin Capsules 25 mg (Batch # 19231858, 19231881, 19233484 and 19233490).

Reserve samples of complaint batch # 19231903 and other four (04) batches (Batch # 19231858, 19231881, 19233484 and 19233490) of product Indomethacin Capsules USP 25mg were inspected for any label of different product present on the bottle and no anomaly was observed. All the bottles were found to be with correct product label of Indomethacin Capsules USP 25mg.

# Indomethacin Capsules USP 25mg

<b>S. No.</b>	<b>NDC</b>	<b>Batch #</b>	<b>Expiry</b>
1.	68462-406-01	19231903	April 2025
2.	68462-406-01	19231858	April 2025
3.	68462-406-01	19231881	April 2025
4.	68462-406-01	19233484	August 2025
5.	68462-406-01	19233490	August 2025