

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 is initiating a market withdrawal at the **Retail level** for the below-identified batches of Clotrimazole Cream USP 1% as an abundance of caution due to broken piercing tips and missing piercing tip defects observed during visual inspection of reserve samples. Glenmark received a market complaint for a broken piercing tip of the cap for Clotrimazole Cream USP 1%, batch# 19252438; 45g tube pack. Glenmark conducted the investigation and identified,

- The reserve samples of the complaint batch# 19252438, and empty tube packing material of batch # 1925P01811 and 1925P04134 used in the complaint batch were physically inspected, and no broken piercing tips or missing piercing tips were observed.
- The reserve samples of all the within-shelf-life batches of Clotrimazole Cream USP 1% packed in 45g tubes were verified, and no broken or missing piercing tips were observed.
- The product Clotrimazole Cream USP 1% is also packed in 15 g and 30 g tube packs. Hence, the visual inspection extrapolated all the within-shelf-life batches of 15 g and 30 g tube pack batches.
- The reserve samples of all the within-shelf-life batches of Clotrimazole Cream USP 1% packed in 30 g tube packs are inspected, and no broken or missing piercing tips were
- Similarly, the reserve samples of all the within-shelf-life batches of Clotrimazole Cream USP 1% packed in 15 g tube packs are inspected, and broken piercing tips and missing piercing tips were observed in three (3) batches. These three (3) Clotrimazole Cream USP 1%, 15 g tube pack batches were packed using a common empty tube packing material batch# 1924P07128.

Since the defects of broken piercing tip and missing piercing tip in the tube cap are associated with only one (1) empty tube packing material batch# 1924P07128 and finished product batches packed using this packing material batch# 1924P07128. The aluminum seals on all these tubes remained intact, confirming that product integrity was not compromised. Hence, as an abundance of caution, Glenmark is initiating a market withdrawal of three (3) batches of Clotrimazole Cream USP 1%, 15 g observed with broken piercing tips and missing piercing tip defects.

Health hazard assessment concluded that the product quality complaint of a broken cap / broken piercing tip/ missing piercing tip is unlikely to have an impact on patient health and safety.

Product name with Strength	NDC Code	Batch No.	Pack Size	Exp. date
Clotrimazole Cream USP 1%	68462- 181-17	19250495	15g tube pack	January 2027

Clotrimazole Cream USP 1%	68462- 181-17	19251113	15g tube pack	February 2027
Clotrimazole Cream USP 1%	68462- 181-17	19251478	15g tube pack	March 2027