

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.

Imiquimod Cream USP 5%
(0.25 g Sachet pack NDC 68462-536-70)

This is to inform you that Glenmark is initiating a voluntary recall involving the following prescription product batches.

This is out of an abundance of precaution because an increasing trend of assay result is observed in product **Imiquimod Cream USP 5%, Batch # 19230562** during long-term stability study.

This batch was charged on stability study as an annual stability monitoring batch for the year 2023. The assay result observed at 18 Months long-term (25°C/60% RH) stability interval is 107% against the specification of NLT 90% and NMT 110% of the labeled amount of Imiquimod. The shelf life of the product is 24 months with the expiry of this Batch # 19230562 as January 2025.

Glenmark changed the laminate (primary packing material) from laminate “PET/ALU/PET/LDPE 4-layer laminate” to alternate new laminate “PAPER/PE/ALU/SURLYN 4-layer laminate”. Upon receipt of PAS approval on November 03, 2021, the change was implemented in February 2022 effective from Batch # 19220797.

The Batch # 19230562 (Manufacturing date: February 2023) was packed with the new laminate PAPER/PE/ALU/SURLYN 4-layer. As of today, in addition to aforementioned batch # 19230562, two batches were charged on stability with the new laminate. Both these batches have completed the stability study till the shelf life of 24 months. Assay results of both the batches at 24 months (shelf life) time point comply with the specification however reported at the higher side of the specification limit.

Since all three batches on stability study with new laminate have shown an increasing trend in Assay results and are nearer to the maximum specification limit of 110% towards the end of shelf life, as an abundance of caution, Glenmark proposes market withdrawal of all the batches of Imiquimod Cream USP 5% that are within-shelf life and packed with new laminate PAPER/PE/ALU/SURLYN 4-layer laminate.

Please see details of product batches listed:

Sr. No.	NDC	Strength	Batch Number	Pack Size	Expiry
1	68462-536-70	5%	19230117	0.25 g Sachet pack	December - 2024
2	68462-536-70	5%	19230225	0.25 g Sachet pack	December - 2024
3	68462-536-70	5%	19230447	0.25 g Sachet pack	January - 2025
4	68462-536-70	5%	19230562	0.25 g Sachet pack	January - 2025
5	68462-536-70	5%	19230688	0.25 g Sachet pack	January - 2025
6	68462-536-70	5%	19230766	0.25 g Sachet pack	January - 2025
7	68462-536-70	5%	19231268	0.25 g Sachet pack	February - 2025
8	68462-536-70	5%	19231312	0.25 g Sachet pack	March - 2025
9	68462-536-70	5%	19231503	0.25 g Sachet pack	March - 2025
10	68462-536-70	5%	19231588	0.25 g Sachet pack	March - 2025
11	68462-536-70	5%	19232359	0.25 g Sachet pack	May - 2025
12	68462-536-70	5%	19232558	0.25 g Sachet pack	May - 2025
13	68462-536-70	5%	19233809	0.25 g Sachet pack	August - 2025
14	68462-536-70	5%	19233971	0.25 g Sachet pack	September - 2025
15	68462-536-70	5%	19234256	0.25 g Sachet pack	September - 2025
16	68462-536-70	5%	19234436	0.25 g Sachet pack	October - 2025
17	68462-536-70	5%	19234677	0.25 g Sachet pack	October - 2025
18	68462-536-70	5%	19234851	0.25 g Sachet pack	November - 2025
19	68462-536-70	5%	19235006	0.25 g Sachet pack	November - 2025
20	68462-536-70	5%	19240226	0.25 g Sachet pack	December - 2025