

*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 Mupirocin Ointment USP 2% at the retail level.

Statistical predictive analysis was performed for the test of Assay for Mupirocin Ointment USP 2% for all the batches on long-term stability manufactured without 5% overages of API (manufactured before February 2025). Based on the statistical predictive analysis, it was observed that Assay results at the terminal time point of 18 months are likely to be towards the lower specification limit, which may fail. Hence, as an abundance of caution, Glenmark proposed and initiated a market withdrawal of batches manufactured without 5% overages of API.

As of today, a total of 128 batches are within shelf life, which are manufactured without 5% overages of API. Glenmark initiated the market withdrawal of 90 batches, effective from September 9, 2025. Glenmark is initiating market withdrawal of the remaining 38 batches of Mupirocin Ointment USP 2% which are manufactured without 5% overages of API (manufactured before February 2025). These 38 batches are within the age of 8 to 10 months, and no OOS failures were reported for the batches proposed under this market withdrawal.

Glenmark has already implemented the revised formulation with the inclusion of 5% overages of API. This change was implemented from February 2025 through PAS approval. The batches proposed for market withdrawal were manufactured before the PAS approval of 5% overages of API.

The Health Hazard Assessment (HHA) conclusion was made based on earlier OOS results (marginally out of specification) in a different batch, which was already recalled. The predicted values of the assay at 18 months in batches proposed for withdrawal indicated these batches also may have borderline OOS results; hence, a Health Hazard assessment was made in line with earlier marginal OOS. The health hazard assessment concluded that the predicted OOS result in the assay is not expected to have any clinically significant effect on efficacy and safety. Hence, the marginal predicted OOS result (near to expiry of the product) is not expected to have any impact on patient health and safety.

#### **Mupirocin Ointment USP 2%**

<b>Sr. No.</b>	<b>NDC Code</b>	<b>Batch Number</b>	<b>Pack size</b>	<b>Expiry Date</b>
1	68462-180-22	19244465	22 g Tube	April-2026
2	68462-180-22	19244472	22 g Tube	April-2026

3	68462-180-22	19244480	22 g Tube	April-2026
4	68462-180-22	19244497	22 g Tube	April-2026
5	68462-180-22	19244522	22 g Tube	April-2026
6	68462-180-22	19244523	22 g Tube	April-2026
7	68462-180-22	19244533	22 g Tube	April-2026
8	68462-180-22	19244559	22 g Tube	April-2026
9	68462-180-22	19244562	22 g Tube	April-2026
10	68462-180-22	19244641	22 g Tube	May-2026
11	68462-180-22	19244653	22 g Tube	May-2026
12	68462-180-22	19244656	22 g Tube	May-2026
13	68462-180-22	19244671	22 g Tube	May-2026
14	68462-180-22	19244686	22 g Tube	May-2026
15	68462-180-22	19244718	22 g Tube	May-2026

16	68462-180-22	19244742	22 g Tube	May-2026
17	68462-180-22	19244755	22 g Tube	May-2026
18	68462-180-22	19244880	22 g Tube	May-2026
19	68462-180-22	19244892	22 g Tube	May-2026
20	68462-180-22	19244924	22 g Tube	May-2026
21	68462-180-22	19250057	22 g Tube	June-2026
22	68462-180-22	19250090	22 g Tube	June-2026
23	68462-180-22	19250104	22 g Tube	June-2026
24	68462-180-22	19250121	22 g Tube	June-2026
25	68462-180-22	19250141	22 g Tube	June-2026
26	68462-180-22	19250199	22 g Tube	June-2026
27	68462-180-22	19250204	22 g Tube	June-2026
28	68462-180-22	19250212	22 g Tube	June-2026

29	68462-180-22	19250234	22 g Tube	June-2026
30	68462-180-22	19250317	22 g Tube	June-2026
31	68462-180-22	19250325	22 g Tube	June-2026
32	68462-180-22	19250352	22 g Tube	June-2026
33	68462-180-22	19250363	22 g Tube	June-2026
34	68462-180-22	19250372	22 g Tube	June-2026
35	68462-180-22	19250374	22 g Tube	June-2026
36	68462-180-22	19250392	22 g Tube	June-2026
37	68462-180-22	19250316	22 g Tube	June-2026
38	68462-180-22	19250436	22 g Tube	June-2026