

DRUG MARKET WITHDRAWAL
MUPIROCIN OINTMENT USP 2%
22 g tube pack
(NDC 68462-180-22)

September 9, 2025

Dear Pharmacy, Wholesale and Retail Customer:

This is to inform you that Glenmark is initiating a Market Withdrawal at the Retail level involving the following prescription product:

Mupirocin Ointment USP 2%

Sr. No.	NDC Code	Batch Number	Pack size	Expiry Date
1	68462-180-22	19241332	22 g Tube	Sep-2025
2	68462-180-22	19241344	22 g Tube	Sep-2025
3	68462-180-22	19241363	22 g Tube	Sep-2025
4	68462-180-22	19241377	22 g Tube	Sep-2025
5	68462-180-22	19241392	22 g Tube	Sep-2025
6	68462-180-22	19241409	22 g Tube	Sep-2025
7	68462-180-22	19241412	22 g Tube	Sep-2025
8	68462-180-22	19241440	22 g Tube	Sep-2025
9	68462-180-22	19241515	22 g Tube	Sep-2025
10	68462-180-22	19241516	22 g Tube	Sep-2025
11	68462-180-22	19241558	22 g Tube	Sep-2025
12	68462-180-22	19241561	22 g Tube	Sep-2025
13	68462-180-22	19241571	22 g Tube	Sep-2025
14	68462-180-22	19241587	22 g Tube	Sep-2025
15	68462-180-22	19241616	22 g Tube	Sep-2025
16	68462-180-22	19241622	22 g Tube	Sep-2025
17	68462-180-22	19241644	22 g Tube	Sep-2025
18	68462-180-22	19241653	22 g Tube	Sep-2025
19	68462-180-22	19241663	22 g Tube	Sep-2025
20	68462-180-22	19241687	22 g Tube	Sep-2025
21	68462-180-22	19241689	22 g Tube	Sep-2025
22	68462-180-22	19241702	22 g Tube	Sep-2025
23	68462-180-22	19241771	22 g Tube	Oct-2025
24	68462-180-22	19241782	22 g Tube	Oct-2025
25	68462-180-22	19241787	22 g Tube	Oct-2025

Sr. No.	NDC Code	Batch Number	Pack size	Expiry Date
26	68462-180-22	19241799	22 g Tube	Oct-2025
27	68462-180-22	19241813	22 g Tube	Oct-2025
28	68462-180-22	19241831	22 g Tube	Oct-2025
29	68462-180-22	19241836	22 g Tube	Oct-2025
30	68462-180-22	19241853	22 g Tube	Oct-2025
31	68462-180-22	19242027	22 g Tube	Oct-2025
32	68462-180-22	19242041	22 g Tube	Oct-2025
33	68462-180-22	19242078	22 g Tube	Oct-2025
34	68462-180-22	19242082	22 g Tube	Oct-2025
35	68462-180-22	19242096	22 g Tube	Oct-2025
36	68462-180-22	19242104	22 g Tube	Oct-2025
37	68462-180-22	19242378	22 g Tube	Nov-2025
38	68462-180-22	19242395	22 g Tube	Nov-2025
39	68462-180-22	19242428	22 g Tube	Nov-2025
40	68462-180-22	19242444	22 g Tube	Nov-2025
41	68462-180-22	19242473	22 g Tube	Nov-2025
42	68462-180-22	19242487	22 g Tube	Nov-2025
43	68462-180-22	19242497	22 g Tube	Nov-2025
44	68462-180-22	19242507	22 g Tube	Nov-2025
45	68462-180-22	19242544	22 g Tube	Nov-2025
46	68462-180-22	19242586	22 g Tube	Dec-2025
47	68462-180-22	19242596	22 g Tube	Dec-2025
48	68462-180-22	19242636	22 g Tube	Dec-2025
49	68462-180-22	19242651	22 g Tube	Dec-2025
50	68462-180-22	19242659	22 g Tube	Dec-2025
51	68462-180-22	19242662	22 g Tube	Dec-2025
52	68462-180-22	19242756	22 g Tube	Dec-2025
53	68462-180-22	19242761	22 g Tube	Dec-2025
54	68462-180-22	19242790	22 g Tube	Dec-2025
55	68462-180-22	19242791	22 g Tube	Dec-2025
56	68462-180-22	19242810	22 g Tube	Dec-2025
57	68462-180-22	19242819	22 g Tube	Dec-2025
58	68462-180-22	19242777	22 g Tube	Dec-2025
59	68462-180-22	19242824	22 g Tube	Dec-2025
60	68462-180-22	19242860	22 g Tube	Dec-2025
61	68462-180-22	19243334	22 g Tube	Jan-2026
62	68462-180-22	19243344	22 g Tube	Jan-2026
63	68462-180-22	19243362	22 g Tube	Jan-2026
64	68462-180-22	19243396	22 g Tube	Jan-2026

Sr. No.	NDC Code	Batch Number	Pack size	Expiry Date
65	68462-180-22	19243416	22 g Tube	Feb-2026
66	68462-180-22	19243425	22 g Tube	Feb-2026
67	68462-180-22	19243438	22 g Tube	Feb-2026
68	68462-180-22	19243466	22 g Tube	Feb-2026
69	68462-180-22	19243480	22 g Tube	Feb-2026
70	68462-180-22	19243555	22 g Tube	Feb-2026
71	68462-180-22	19243568	22 g Tube	Feb-2026
72	68462-180-22	19243628	22 g Tube	Feb-2026
73	68462-180-22	19243643	22 g Tube	Feb-2026
74	68462-180-22	19243656	22 g Tube	Feb-2026
75	68462-180-22	19243813	22 g Tube	Mar-2026
76	68462-180-22	19243829	22 g Tube	Mar-2026
77	68462-180-22	19243843	22 g Tube	Mar-2026
78	68462-180-22	19243858	22 g Tube	Mar-2026
79	68462-180-22	19243873	22 g Tube	Mar-2026
80	68462-180-22	19243891	22 g Tube	Mar-2026
81	68462-180-22	19243899	22 g Tube	Mar-2026
82	68462-180-22	19243910	22 g Tube	Mar-2026
83	68462-180-22	19243938	22 g Tube	Mar-2026
84	68462-180-22	19244250	22 g Tube	Apr-2026
85	68462-180-22	19244262	22 g Tube	Apr-2026
86	68462-180-22	19244273	22 g Tube	Apr-2026
87	68462-180-22	19244289	22 g Tube	Apr-2026
88	68462-180-22	19244299	22 g Tube	Apr-2026
89	68462-180-22	19244362	22 g Tube	Apr-2026
90	68462-180-22	19250407	22 g Tube	Jun-2026

Glenmark is initiating a market withdrawal at the **Retail level** for the above-identified batches of Mupirocin Ointment USP 2%.

The batches proposed for market withdrawal are manufactured without 5% overages of API with 18 month shelf life. Based on review of stability trend for Assay test and the extrapolation of Assay results up to 18 month shelf life stability interval, the predicted Assay results are likely to be on the borderline at lower specification limit or may marginally fail at 18 months interval. Hence as an abundance of caution, all the batches that are manufactured without 5% overages of API with 18 month shelf life are proposed for Market Withdrawal.

Glenmark has already implemented revised formulation with inclusion of 5% overages of API. This change was implemented from February 2025 through PAS approval.



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. The marginal OOS result (observed near to expiry of the product) is not expected to have any impact on patient health and safety.

Please see the details of product batches listed in the above table and refer to the enclosed product labels for ease in identifying the product.

Please examine your inventory, and if you have any inventory available for the batches specified in the above table, you should quarantine such product immediately and not dispense any further product from these lots. Glenmark Pharmaceuticals Inc., USA, initiated shipment of this product on April 30, 2024.

In addition, if you are a wholesaler/ distributor who has further distributed this product, please identify those retail customers and notify them at once of this market withdrawal. Your notification to your retail customers may be enhanced by including a copy of this market withdrawal notification letter. Again, this market withdrawal should be carried out to the retail level only. Because this is not a consumer-level market withdrawal, notice to the consumer level is not required.

Glenmark is requesting the batches specified in the above table to be returned to Inmar Rx Solutions (address below) using the Postage Paid Product Return label that was provided in your Market Withdrawal Return Packet.

Inmar Rx Solutions
3845 Grand Lakes Way
Grand Prairie, TX 75050

Please complete and return the enclosed response form preferably within 72 hours of receipt of this notification. Please either fax your response to 817-868-5362 or email to Rxrecalls@Inmar.com.

If you have any questions regarding your market withdrawal return please contact Inmar at **877-874-7340**

Inmar office hours are Monday through Friday, from 9 am to 5 pm EST.

This market withdrawal is being made with the knowledge of the Food and Drug Administration.

Thank you for your cooperation,

Sincerely,

GLENMARK PHARMACEUTICALS INC., USA

thomas.callaghan@glenmarkpharma.com
Digitally signed by
thomas.callaghan@glenmarkpharm
a.com
Date: 2025.09.09 09:55:39 -04'00'

Thomas Callaghan

Executive Director - Regulatory Affairs, North America

US Agent for Glenmark Pharmaceuticals Limited

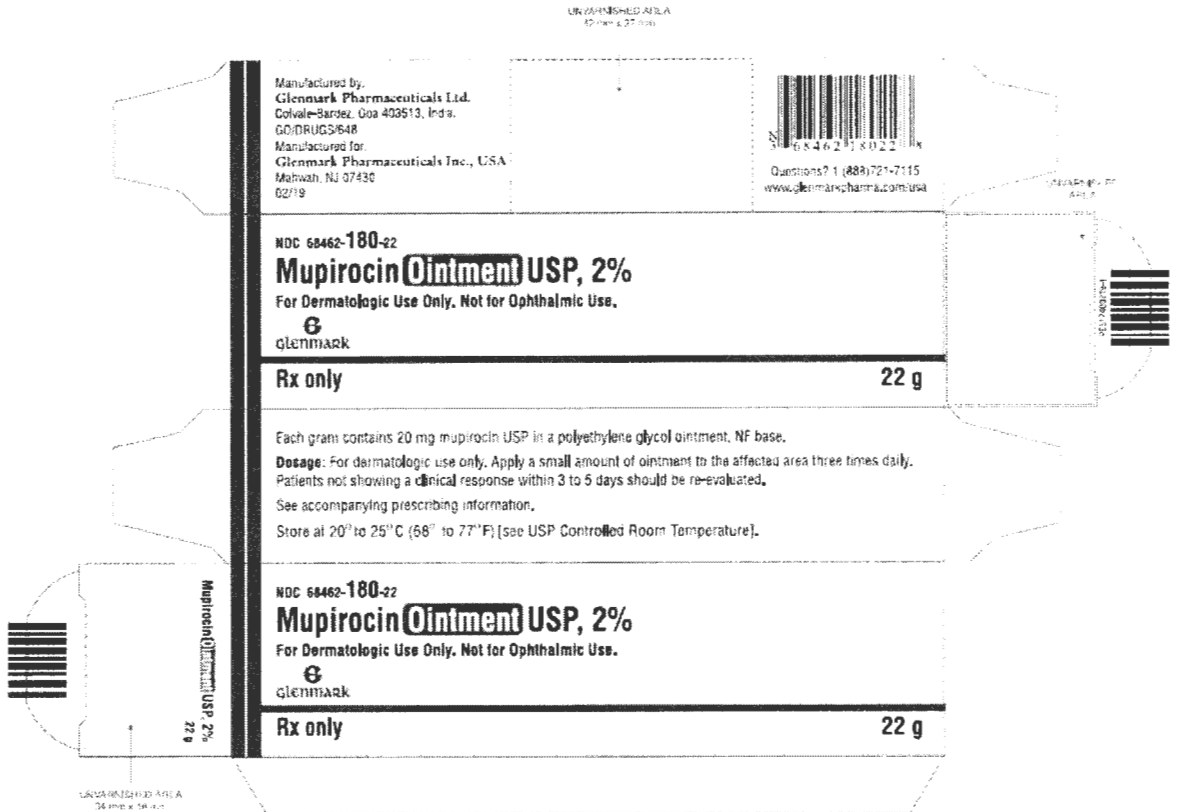
Enclosure(s):

Product Labels

Market Withdrawal Return Response Form

Product label:

Mupirocin Ointment USP 2%



MARKET WITHDRAWAL RETURN RESPONSE FORM

MUPIROCIN OINTMENT USP 2%

22 g tube pack

(NDC 68462-180-22)

Retail Level

9/9/2025

Please fill out this form completely. By doing so, this will acknowledge that you have read and understand the withdrawal instructions and have taken the appropriate action.

Customer Name:	DEA#:
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DEA # is required, if it is not provided, the processing of your form will be delayed.

Address:		
City:	State:	Zip:

Contact Name (Please Print):		
Telephone#:	Email:	
Contact Signature:	Date:	

DEBIT MEMO# (If unsure, leave blank):

Wholesaler Information if not directly purchased from Glenmark Pharmaceuticals Inc.:

Wholesaler Name:	DEA#:
City:	State: Zip:

I have checked my stock and communicated to my customers at the appropriate level:

☐ I confirm that all locations that received the impacted products have been notified to the Retail level _____ (Initial and date)

☐ I do not have any stock of the market withdrawn items. **OR**

☐ I have quarantined and listed in the box below the quantity of market withdrawn units and I will be returning to Inmar, as soon as possible. Upon receipt of this Response Form, Inmar, will issue return authorization label(s)

Please indicate the # of needed box labels _____

Mupirocin Ointment USP 2%

Sr. No.	NDC Code	Batch Number	Pack size	Expiry Date	Total Full/ Sealed and Partial/ Open Tube Count
1	68462-180-22	19241332	22 g Tube	Sep-2025	
2	68462-180-22	19241344	22 g Tube	Sep-2025	
3	68462-180-22	19241363	22 g Tube	Sep-2025	
4	68462-180-22	19241377	22 g Tube	Sep-2025	
5	68462-180-22	19241392	22 g Tube	Sep-2025	
6	68462-180-22	19241409	22 g Tube	Sep-2025	
7	68462-180-22	19241412	22 g Tube	Sep-2025	
8	68462-180-22	19241440	22 g Tube	Sep-2025	
9	68462-180-22	19241515	22 g Tube	Sep-2025	
10	68462-180-22	19241516	22 g Tube	Sep-2025	
11	68462-180-22	19241558	22 g Tube	Sep-2025	
12	68462-180-22	19241561	22 g Tube	Sep-2025	
13	68462-180-22	19241571	22 g Tube	Sep-2025	
14	68462-180-22	19241587	22 g Tube	Sep-2025	
15	68462-180-22	19241616	22 g Tube	Sep-2025	
16	68462-180-22	19241622	22 g Tube	Sep-2025	
17	68462-180-22	19241644	22 g Tube	Sep-2025	
18	68462-180-22	19241653	22 g Tube	Sep-2025	
19	68462-180-22	19241663	22 g Tube	Sep-2025	
20	68462-180-22	19241687	22 g Tube	Sep-2025	
21	68462-180-22	19241689	22 g Tube	Sep-2025	
22	68462-180-22	19241702	22 g Tube	Sep-2025	
23	68462-180-22	19241771	22 g Tube	Oct-2025	
24	68462-180-22	19241782	22 g Tube	Oct-2025	
25	68462-180-22	19241787	22 g Tube	Oct-2025	
26	68462-180-22	19241799	22 g Tube	Oct-2025	
27	68462-180-22	19241813	22 g Tube	Oct-2025	
28	68462-180-22	19241831	22 g Tube	Oct-2025	
29	68462-180-22	19241836	22 g Tube	Oct-2025	
30	68462-180-22	19241853	22 g Tube	Oct-2025	
31	68462-180-22	19242027	22 g Tube	Oct-2025	
32	68462-180-22	19242041	22 g Tube	Oct-2025	
33	68462-180-22	19242078	22 g Tube	Oct-2025	
34	68462-180-22	19242082	22 g Tube	Oct-2025	
35	68462-180-22	19242096	22 g Tube	Oct-2025	
36	68462-180-22	19242104	22 g Tube	Oct-2025	
37	68462-180-22	19242378	22 g Tube	Nov-2025	
38	68462-180-22	19242395	22 g Tube	Nov-2025	
39	68462-180-22	19242428	22 g Tube	Nov-2025	
40	68462-180-22	19242444	22 g Tube	Nov-2025	
41	68462-180-22	19242473	22 g Tube	Nov-2025	
42	68462-180-22	19242487	22 g Tube	Nov-2025	
43	68462-180-22	19242497	22 g Tube	Nov-2025	
44	68462-180-22	19242507	22 g Tube	Nov-2025	
45	68462-180-22	19242544	22 g Tube	Nov-2025	
46	68462-180-22	19242586	22 g Tube	Dec-2025	
47	68462-180-22	19242596	22 g Tube	Dec-2025	
48	68462-180-22	19242636	22 g Tube	Dec-2025	

Sr. No.	NDC Code	Batch Number	Pack size	Expiry Date	Total Full/ Sealed and Partial/ Open Tube Count
49	68462-180-22	19242651	22 g Tube	Dec-2025	
50	68462-180-22	19242659	22 g Tube	Dec-2025	
51	68462-180-22	19242662	22 g Tube	Dec-2025	
52	68462-180-22	19242756	22 g Tube	Dec-2025	
53	68462-180-22	19242761	22 g Tube	Dec-2025	
54	68462-180-22	19242790	22 g Tube	Dec-2025	
55	68462-180-22	19242791	22 g Tube	Dec-2025	
56	68462-180-22	19242810	22 g Tube	Dec-2025	
57	68462-180-22	19242819	22 g Tube	Dec-2025	
58	68462-180-22	19242777	22 g Tube	Dec-2025	
59	68462-180-22	19242824	22 g Tube	Dec-2025	
60	68462-180-22	19242860	22 g Tube	Dec-2025	
61	68462-180-22	19243334	22 g Tube	Jan-2026	
62	68462-180-22	19243344	22 g Tube	Jan-2026	
63	68462-180-22	19243362	22 g Tube	Jan-2026	
64	68462-180-22	19243396	22 g Tube	Jan-2026	
65	68462-180-22	19243416	22 g Tube	Feb-2026	
66	68462-180-22	19243425	22 g Tube	Feb-2026	
67	68462-180-22	19243438	22 g Tube	Feb-2026	
68	68462-180-22	19243466	22 g Tube	Feb-2026	
69	68462-180-22	19243480	22 g Tube	Feb-2026	
70	68462-180-22	19243555	22 g Tube	Feb-2026	
71	68462-180-22	19243568	22 g Tube	Feb-2026	
72	68462-180-22	19243628	22 g Tube	Feb-2026	
73	68462-180-22	19243643	22 g Tube	Feb-2026	
74	68462-180-22	19243656	22 g Tube	Feb-2026	
75	68462-180-22	19243813	22 g Tube	Mar-2026	
76	68462-180-22	19243829	22 g Tube	Mar-2026	
77	68462-180-22	19243843	22 g Tube	Mar-2026	
78	68462-180-22	19243858	22 g Tube	Mar-2026	
79	68462-180-22	19243873	22 g Tube	Mar-2026	
80	68462-180-22	19243891	22 g Tube	Mar-2026	
81	68462-180-22	19243899	22 g Tube	Mar-2026	
82	68462-180-22	19243910	22 g Tube	Mar-2026	
83	68462-180-22	19243938	22 g Tube	Mar-2026	
84	68462-180-22	19244250	22 g Tube	Apr-2026	
85	68462-180-22	19244262	22 g Tube	Apr-2026	
86	68462-180-22	19244273	22 g Tube	Apr-2026	
87	68462-180-22	19244289	22 g Tube	Apr-2026	
88	68462-180-22	19244299	22 g Tube	Apr-2026	
89	68462-180-22	19244362	22 g Tube	Apr-2026	
90	68462-180-22	19250407	22 g Tube	Jun-2026	

If you have any questions regarding this form or product return please contact Inmar at 877-874-7340 Office hours 9am to 5pm EST Mon thru Fri.

Please fax this form to: 1-817-868-5362 or E-mail rxrecalls@inmar.com

Market Withdrawal Event ID N131358 | RCL229-25

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