



URGENT: DRUG RECALL

MUPIROCIN OINTMENT USP, 2%, 22 g Tube pack (OINTMENT) (NDC 68462-180-22)

August 30, 2024

Dear Customer,

This is to inform you of a voluntary recall to Wholesale level involving the following drug product:

Mupirocin Ointment USP, 2%

Sr. No.	NDC	Batch Number	Expiry Date
1	68462-180-22	19223615	Aug-2024
2	68462-180-22	19223537	Aug-2024
3	68462-180-22	19223544	Aug-2024
4	68462-180-22	19223568	Aug-2024
5	68462-180-22	19223593	Aug-2024
6	68462-180-22	19223641	Aug-2024
7	68462-180-22	19224055	Sep-2024
8	68462-180-22	19224281	Sep-2024
9	68462-180-22	19224307	Sep-2024
10	68462-180-22	19224321	Sep-2024
11	68462-180-22	19224341	Sep-2024
12	68462-180-22	19224467	Sep-2024
13	68462-180-22	19224525	Oct-2024
14	68462-180-22	19224542	Oct-2024
15	68462-180-22	19224560	Oct-2024
16	68462-180-22	19224580	Oct-2024
17	68462-180-22	19224990	Nov-2024
18	68462-180-22	19224998	Nov-2024
19	68462-180-22	19225014	Nov-2024
20	68462-180-22	19225033	Nov-2024
21	68462-180-22	19225293	Nov-2024

Sr. No.	NDC	Batch Number	Expiry Date
22	68462-180-22	19225304	Nov-2024
23	68462-180-22	19225320	Nov-2024
24	68462-180-22	19225349	Nov-2024
25	68462-180-22	19225367	Nov-2024
26	68462-180-22	19225379	Nov-2024
27	68462-180-22	19225401	Nov-2024
28	68462-180-22	19230115	Dec-2024
29	68462-180-22	19230123	Dec-2024
30	68462-180-22	19230132	Dec-2024
31	68462-180-22	19230137	Dec-2024
32	68462-180-22	19230167	Dec-2024
33	68462-180-22	19230170	Dec-2024
34	68462-180-22	19230572	Jan-2025
35	68462-180-22	19230607	Jan-2025
36	68462-180-22	19230614	Jan-2025
37	68462-180-22	19230628	Jan-2025
38	68462-180-22	19230631	Jan-2025
39	68462-180-22	19230874	Feb-2025
40	68462-180-22	19230925	Feb-2025
41	68462-180-22	19230941	Feb-2025
42	68462-180-22	19230957	Feb-2025
43	68462-180-22	19230976	Feb-2025
44	68462-180-22	19231232	Feb-2025
45	68462-180-22	19231238	Feb-2025
46	68462-180-22	19231282	Feb-2025
47	68462-180-22	19231285	Feb-2025

Recall of these batches have been initiated due to an out-of-specification result reported for the Assay test for batch# 19223615 at the 18 months long-term (25°C/60% RH) stability time point. The age of the batch at the time of testing was 23 months from the date of batch manufacturing and the shelf-life of the batch is 24 months with an expiry of August 2024.



As an impact assessment, reserve samples of seven (7) batches aging from 21 to 24 months old were tested for the test of assay. Out of these seven (7) batches, three (3) batches do not comply with the specification. The remaining four (4) batches do comply with the specification; however, towards the lower side of the limit.

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 that pertains to the batches as specified in above table then quarantine these batches immediately. Glenmark Pharmaceuticals, Inc. initiated shipment of this product on October 25th, 2022.

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 Recall 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 recall return please contact Inmar at 877-899-0981

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

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

Thank you for your cooperation,

Sincerely,

GLENMARK PHARMACEUTICALS INC., USA

**Thomas
Callaghan**

Digitally signed by Thomas
Callaghan
Date: 2024.08.30 07:57:48
-04'00'

Thomas Callaghan

Executive Director - Regulatory Affairs, North America

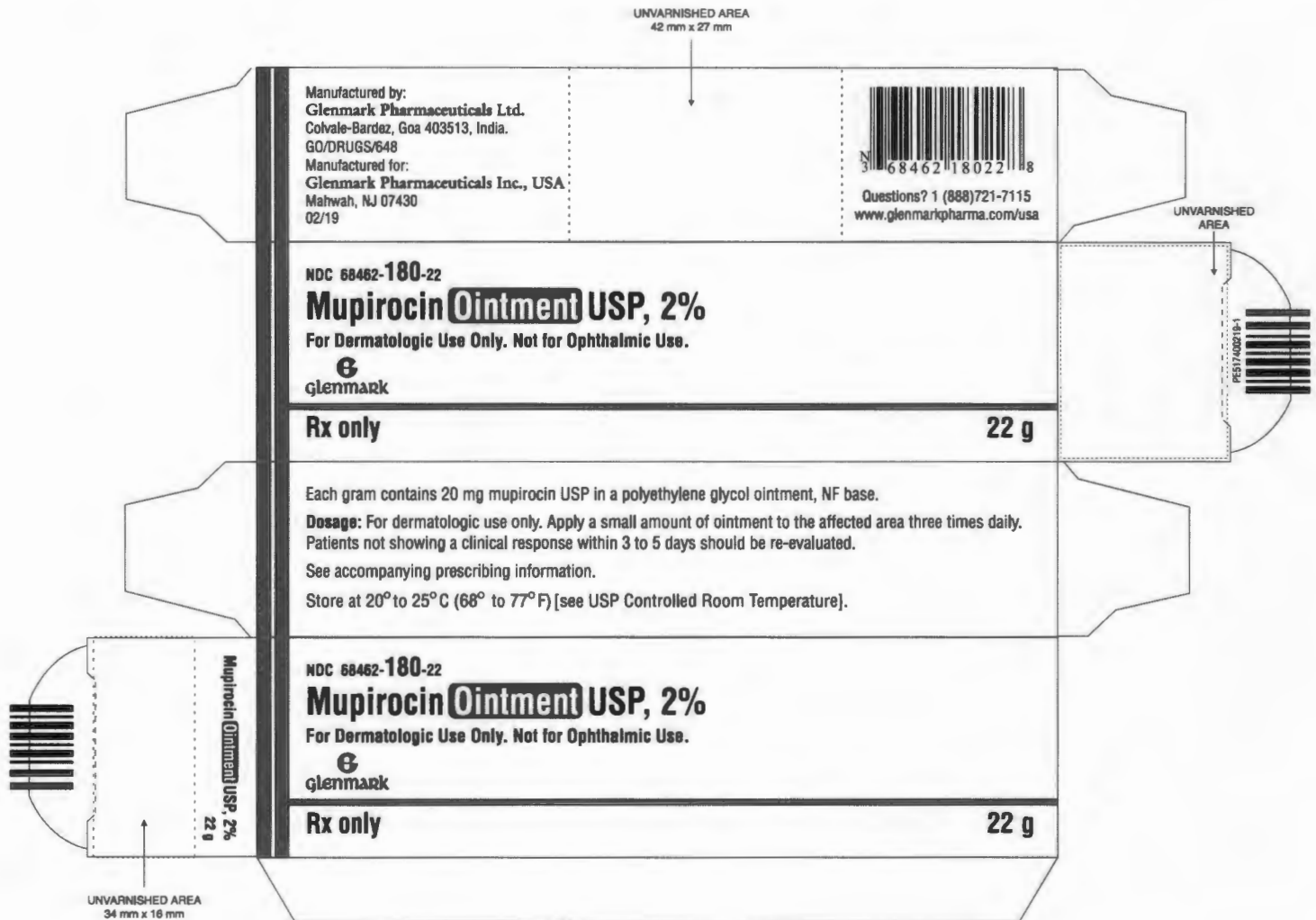
US Agent for Glenmark Pharmaceuticals

Enclosure(s):

Product Labels

Recall Return Response Form

SAME SIZE ARTWORK
 CARTON SIZE: 125 mm X 34 mm X 27 mm



Prathyus
 ha
 Reddy
 Challa

Digitally signed
 by Prathyusha
 Reddy Challa
 Date:
 2019.02.25
 14:13:25 -05'00'

GLENMARK PHARMACEUTICALS LTD.	DATE:	PANTONE SHADE NO: BLACK 186 C 364 C	
	PRODUCT NAME: Mupirocin Ointment	PKG. DEV.:	Item code, Version, Consistency of Design, overprint area, Pack size, Dimensions & Layout
ITEM CODE: PE51740 VERSION: 0219-1	RA	Regulatory Text	
PHARMACODE: 874	QA:	Entire Text	
COUNTRY: USA	PRODUCTION:	Machine Suitability	
LOCATION: COLVALE - GOA	REMARKS:		
PACK : CARTON - 22 g			
ACTUAL SIZE: 125 mm x 34 mm x 27 mm			
SPECIFICATION: 300 GSM ITC Cyber XL with Aqua varnish except for the area marked			

Dr. Qun
 Luo

Digitally signed
 by Dr. Qun Luo
 Date: 2019.02.25
 14:36:58 -05'00'

Carole
 Capella

Digitally signed
 by Carole Capella
 Date: 2019.02.25
 14:48:07 -05'00'



Glenmark Pharmaceuticals Inc.
RECALL RETURN RESPONSE FORM
MUPIROCIN OINTMENT USP, 2% 22 g Tube pack
NDC 68462-180-22
Wholesale Level
08/30/2024

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

Customer Name:	DEA#:
<i>DEA # is required, if it is not provided, the processing of your form will be delayed.</i>	
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 Wholesale level _____ (Initial and date)

I do not have any stock of the recalled items.

OR

I have quarantined and listed in the box below the quantity of recalled 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 _____.

Sr. No.	Item Description	NDC#	Lot#	Exp. Date	Total Full/Sealed and Partial/Open Tube Count
1	MUPIROCIN OINTMENT USP 2%	68462-180-22	19223615	Aug-2024	
2	MUPIROCIN OINTMENT USP 2%	68462-180-22	19223537	Aug-2024	
3	MUPIROCIN OINTMENT USP 2%	68462-180-22	19223544	Aug-2024	
4	MUPIROCIN OINTMENT USP 2%	68462-180-22	19223568	Aug-2024	

Sr. No.	Item Description	NDC#	Lot#	Exp. Date	Total Full/Sealed and Partial/Open Tube Count
5	MUPIROCIN OINTMENT USP 2%	68462-180-22	19223593	Aug-2024	
6	MUPIROCIN OINTMENT USP 2%	68462-180-22	19223641	Aug-2024	
7	MUPIROCIN OINTMENT USP 2%	68462-180-22	19224055	Sep-2024	
8	MUPIROCIN OINTMENT USP 2%	68462-180-22	19224281	Sep-2024	
9	MUPIROCIN OINTMENT USP 2%	68462-180-22	19224307	Sep-2024	
10	MUPIROCIN OINTMENT USP 2%	68462-180-22	19224321	Sep-2024	
11	MUPIROCIN OINTMENT USP 2%	68462-180-22	19224341	Sep-2024	
12	MUPIROCIN OINTMENT USP 2%	68462-180-22	19224467	Sep-2024	
13	MUPIROCIN OINTMENT USP 2%	68462-180-22	19224525	Oct-2024	
14	MUPIROCIN OINTMENT USP 2%	68462-180-22	19224542	Oct-2024	
15	MUPIROCIN OINTMENT USP 2%	68462-180-22	19224560	Oct-2024	
16	MUPIROCIN OINTMENT USP 2%	68462-180-22	19224580	Oct-2024	
17	MUPIROCIN OINTMENT USP 2%	68462-180-22	19224990	Nov-2024	
18	MUPIROCIN OINTMENT USP 2%	68462-180-22	19224998	Nov-2024	
19	MUPIROCIN OINTMENT USP 2%	68462-180-22	19225014	Nov-2024	
20	MUPIROCIN OINTMENT USP 2%	68462-180-22	19225033	Nov-2024	
21	MUPIROCIN OINTMENT USP 2%	68462-180-22	19225293	Nov-2024	
22	MUPIROCIN OINTMENT USP 2%	68462-180-22	19225304	Nov-2024	
23	MUPIROCIN OINTMENT USP 2%	68462-180-22	19225320	Nov-2024	
24	MUPIROCIN OINTMENT USP 2%	68462-180-22	19225349	Nov-2024	
25	MUPIROCIN OINTMENT USP 2%	68462-180-22	19225367	Nov-2024	
26	MUPIROCIN OINTMENT USP 2%	68462-180-22	19225379	Nov-2024	
27	MUPIROCIN OINTMENT USP 2%	68462-180-22	19225401	Nov-2024	
28	MUPIROCIN OINTMENT USP 2%	68462-180-22	19230115	Dec-2024	
29	MUPIROCIN OINTMENT USP 2%	68462-180-22	19230123	Dec-2024	
30	MUPIROCIN OINTMENT USP 2%	68462-180-22	19230132	Dec-2024	
31	MUPIROCIN OINTMENT USP 2%	68462-180-22	19230137	Dec-2024	
32	MUPIROCIN OINTMENT USP 2%	68462-180-22	19230167	Dec-2024	
33	MUPIROCIN OINTMENT USP 2%	68462-180-22	19230170	Dec-2024	
34	MUPIROCIN OINTMENT USP 2%	68462-180-22	19230572	Jan-2025	
35	MUPIROCIN OINTMENT USP 2%	68462-180-22	19230607	Jan-2025	
36	MUPIROCIN OINTMENT USP 2%	68462-180-22	19230614	Jan-2025	
37	MUPIROCIN OINTMENT USP 2%	68462-180-22	19230628	Jan-2025	
38	MUPIROCIN OINTMENT USP 2%	68462-180-22	19230631	Jan-2025	
39	MUPIROCIN OINTMENT USP 2%	68462-180-22	19230874	Feb-2025	
40	MUPIROCIN OINTMENT USP 2%	68462-180-22	19230925	Feb-2025	
41	MUPIROCIN OINTMENT USP 2%	68462-180-22	19230941	Feb-2025	
42	MUPIROCIN OINTMENT USP 2%	68462-180-22	19230957	Feb-2025	
43	MUPIROCIN OINTMENT USP 2%	68462-180-22	19230976	Feb-2025	

Sr. No.	Item Description	NDC#	Lot#	Exp. Date	Total Full/Sealed and Partial/Open Tube Count
44	MUPIROCIN OINTMENT USP 2%	68462-180-22	19231232	Feb-2025	
45	MUPIROCIN OINTMENT USP 2%	68462-180-22	19231238	Feb-2025	
46	MUPIROCIN OINTMENT USP 2%	68462-180-22	19231282	Feb-2025	
47	MUPIROCIN OINTMENT USP 2%	68462-180-22	19231285	Feb-2025	

If you have any questions regarding this form or product return please contact Inmar at 877-899-0981
Office hours 9am to 5pm EST Mon thru Fri.

**Please fax this form to: 1-817-868-5362 or E-mail rxrecalls@inmar.com
Recall Event ID RCL221-24 / N131208**