

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 192253		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	34 68462-180-22 19230572 35 68462-180-22 19230607		Jan-2025			
35			Jan-2025			
36	68462-180-22	17200011				
37	68462-180-22					
38	68462-180-22	19230631	Jan-2025			
39	68462-180-22	68462-180-22 19230874				
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
Digitally signed by Thomas
Callaghan
Date: 2024.08.30 07:57:48

Callaghan Date: 20

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 188 C 364 C	
PRODUCT NAME: Mupirocin Ointment ITEM CODE: PE51740 VERSION: 0219-1	PKG. DEV.:	Item code, Version, Consistency of Design, overprint area, Pack size, Dimensions & Layout	
PHARMACODE: 874	RA	Regulatory Text	
COUNTRY: USA	QA:	Entire Text	
LOCATION: COLVALE - GOA PACK: CARTON - 22 g	PRODUCTION:	Machine Suitability	
ACTUAL SIZE:125 mm x 34 mm x 27 mm	REMARKS:		

Dr. Qun Luo Digitally signed by Dr. Qun Luo Date: 2019.02.25 14:36:58 -05'00' Carole Digitally signed by Carole Capella Date: 2019.02.25 14:48:07-05'00'

May

Breedlove

Digitally signed by May Breedlove Date: 2021.09.08 08:49:46 -04'00'

PHARMACODE: NA TTEM CODE: PESSO: PRODUCT NAME: MUPIROCIN

0821-

PKG. DATE: 24-08-2021 N30

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GLENMARK PHARMACEUTICALS LTD

ACTUAL SIZE: PACK COUNTRY:

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PATIENT INFORMATION Mupirocia (mue-PIR-eh-sin) Ointment

What is mupirocin cintment?

Mupirocin ointment is a prescription medicine used on the skin (topical use) to treat a skin infection called impetigo that is caused by bacteria called Staphylococcus aureus and Streptococcus pyogenes. It is not known if mupirocin ointment is safe and effective in children under 2 months of age.

Who should not use mapirooin eintment?

De set use musireels eletement it:

• you are allergic to mupirecin or any of the ingredients in mupirecin ointment.

See the end of this Patient Information leaflet for a complete list of the ingredients in mupirocin ointment.

What should I tell my healthcare provider before using mupirocin eintment? Before using mupirocia eintment, tell your healthcare provider about all of your medical conditions including if you:

· have kidney problems

· are pregnant or plan to become pregnant. It is not known if mupirocin contrnent

will harm your unborn baby. · are breastfeeding or plan to breastfeed. It is not known if mupirocin ointment passes into your breast milk. You and your healthcare provider should decide if you can use mupirocin ointment while breastfeeding.

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Do not mix mupirocin cintment with other lotions, creams, or cintments.

How should I use mustrects eintment? Mapleveta elatment is for use on the skie (topical). Do not get mupirocin ointment in your eyes, nose, mouth, or vagina (mucosal surfaces).

. Use mupirocin ointment exactly as your healthcare provider tells you to use it. . Apply a small amount of mupirocin ointment, with a cotton swab or gauze pad, to the affected area 3 times each day.

. It is important that you take the full course of mupirocin ointment. Do not stop early because your symptoms may disappear before the infection is fully cleared.

 Wash your hands before and after applying mupirocin ointment.
 After applying mupirocin ointment, you may cover the treated area with a clean. gauze pad, unless your healthcare provider has told you to leave it uncovered.

. Talk to your healthcare provider if your skin does not improve after 3 to 5 days of treatment with mupirocin ointment.

. If you are breastfeeding and use mupirocin ointment on your breast or nipple, wash the area well before breastfeeding your child.

What are the possible side effects of mapirocin aintment? Mapirocin ointment may cause serious side effects, including:

. severe allergic reactions. Stop using mupirocin ointment and call your healthcare provider or go to the nearest emergency room right away if you have any of the following signs or symptoms of a severe allergic reaction: o hives

· trouble breathing or wheezing o swelling of your face, lips, mouth, or o dizziness, fast heartbeat or tongue pounding in your chest

· a rash over your whole body · eye inflation. Do not get mupirocin ointment in your eyes. If mupirocin ointment gets in your eyes, rinse your eyes well with water.

· irritation in the area mupirouin eletment to used. Stop using mupirocin ointment and call your heelthcare provider if you develop an irritation, severe itching, or a rash while using mupirocin ointment.

Kristin DiStefano

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Manufactured for: 6 **glenmark**

Glenmark Pharmaceuticals Inc., USA

Questions? 1 (888) 721-7115

This Patient Information has been approved by the U.S. Food and Drug Administration. Revised: August 2021

 a type of diarrhea called cleatridium difficile-asseciated diarrhea (CDAD).
 CDAD may happen in people who use or have used medicine to treat bacterial infections. The severity of CDAD can range from mild diarrhea to severe diarrhea that may cause death (fatal colitis). Call your healthcare provider or go to the nearest emergency room right away if you have diarrhea while using

or after you stop using mupirocin olintment.

• rake of absorption of polyethylene glysol through the akin. Mupirocin olintment contains polyethylene glysol, which in large amounts can cause kidney damage. You should not apply mupirocin olintment to open skin wounds or damaged skin, especially if you have kidney problems.

· increased risk of infection at IV (intravenous) sites. Mupirocin contraent should not be used on skin that is near an IV (intravenous) site.

The most common side effects of mupirocin ointment include:

burning

stinging or pain
ltching

These are not all the possible side effects of mupirocin ointment. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store mupirocia eintment?

. Store mupirocin ointment at room temperature between 68°F to 77°F (20°C to 25°C).

. Keep mupirocin cintment and all medicines out of the reach of children.

General information about the safe and effective use of mapirocin clatment Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use mupirocin ointment for a condition for which it was not prescribed. Do not give mupirocin ointment to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about mupirocin ointment that is written for health professionals.

What are the ingredients in musired eintment? Active ingredient: mupirocin inactive ingredients: polyethylene glycol 400 and polyethylene glycol 3350

Trademarks are the property of their respective owners.

Manufactured by: Gleamark Pharmacouticals Limited Colvale-Bardez, Goa 403513, India

Mahwah, NJ 07430

www.glenmarkpharma-us.com

Printed Purforation

Digitally signed by May Breedlove Date: 2021.09.08 08:49:57 -04'00' Breedlove May

Capella Carole

SPECIFICATION: 28 GSM Bible Pape Digitally signed by Carole Capella Date: 2021.09.08

240 x 430 mm

ACTUAL SIZE:

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PKG. DEV.:

VERSION: 0821-

MACODE: NA

COUNTRY

ITEM CODE: PESSO USA

DATE: 24-08-2021

& GLENMARK PHARMACEUTICALS LTD

IUCT NAME: MUPIROCIN DINTMENT 2% US LF



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

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

Customer Name:			DEA#:		
DEA # is required	d, if it is not prov	rided, the proce	ssing of your form	will be delayed.	
Address:					
City:			State:	Zip:	
Contact Name (Please Print):					
Telephone#:	Ema	ail:			
Contact Signature:			Date:		
DEBIT MEMO# (If unsure, leave b	olank):				
Wholesaler Information if not dir	ectly purchased	from Glenma	rk Pharmaceutics	als Inc.:	
Wholesaler Name:	ectly purchased	from Glenma	DEA#:		
	ectly purchased	from Glenma		Zip:	
Wholesaler Name: City: I have checked my stock and comm	nunicated to my	customers at	DEA#: State:	Zip:	
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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	
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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	
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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	-	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