glenmark
A new way for a new world

DRUG MARKET WITHDRAWAL

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

September 29, 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	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

Glenmark Pharmaceuticals Inc. USA 750 Corporate Drive, Mahwah, NJ 07430
T: 1 201 684 8000 F: 1 201 831 0080 www.glenmarkpharma.com/usa

Sr. No.	NDC Code	Batch Number	Pack size	Expiry Date
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

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

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

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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.

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 December 10, 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 **855-850-3305.**

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.

Glenmark Pharmaceuticals Inc. USA 750 Corporate Drive, Mahwah, NJ 07430
T: 1 201 684 8000 F: 1 201 831 0080 www.glenmarkpharma.com/usa

Thank you for your cooperation,

Sincerely,

GLENMARK PHARMACEUTICALS INC., USA

Thomas Callaghan Digitally signed by Thomas Callaghan
Date: 2025.09.29 08:18:36 -04'00'

Thomas Callaghan

Executive Director - Regulatory Affairs, North America

US Agent for Glenmark Pharmaceuticals Limited

Enclosure(s):

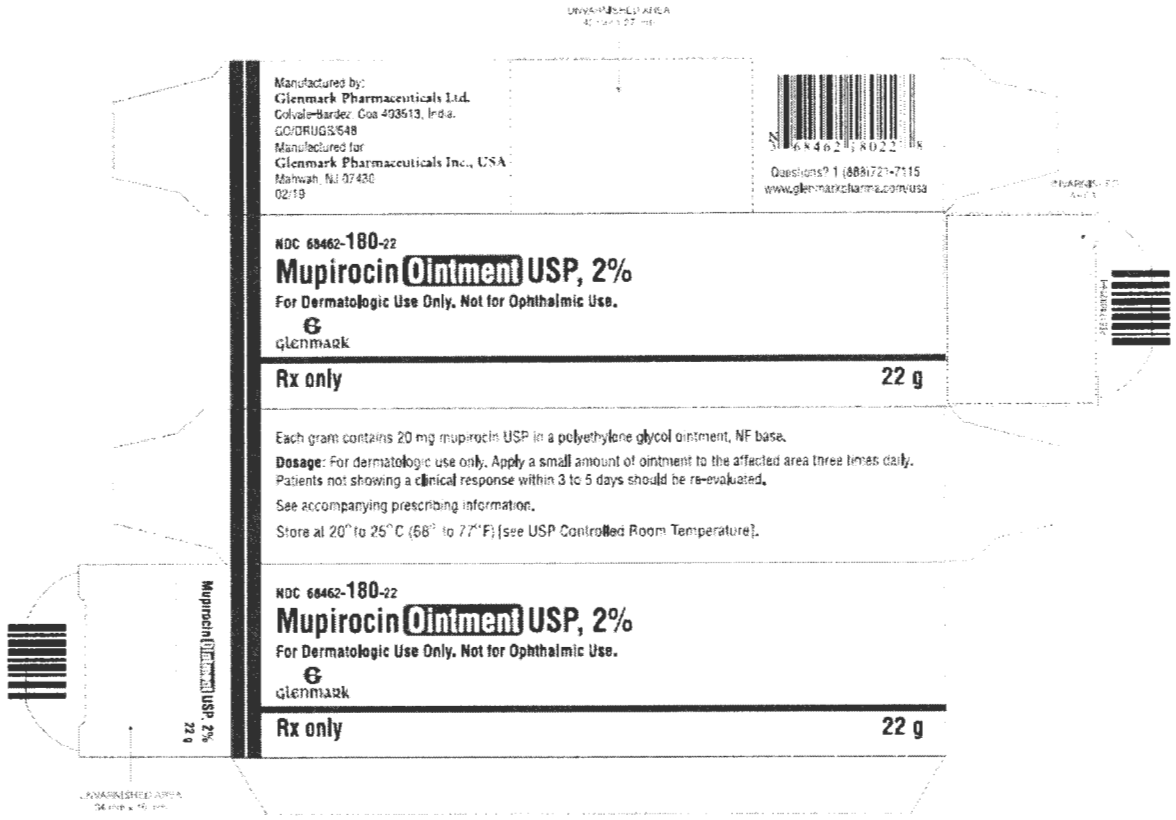
Product Labels

Market Withdrawal Return Response Form.

Glenmark Pharmaceuticals Inc. USA 750 Corporate Drive, Mahwah, NJ 07430
T: 1 201 684 8000 F: 1 201 831 0080 www.glenmarkpharma.com/usa

Product label:

Mupirocin Ointment USP 2%



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MARKET WITHDRAWAL RETURN RESPONSE FORM

MUPIROCIN OINTMENT USP 2%
22 g tube pack
(NDC 68462-180-22)
Retail Level
9/29/2025

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#:

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	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	

If you have any questions regarding this form or product return, please contact Inmar at **855-850-3305**. Office hours are 9:00 a.m. to 5:00 p.m. EST, Monday through Friday.

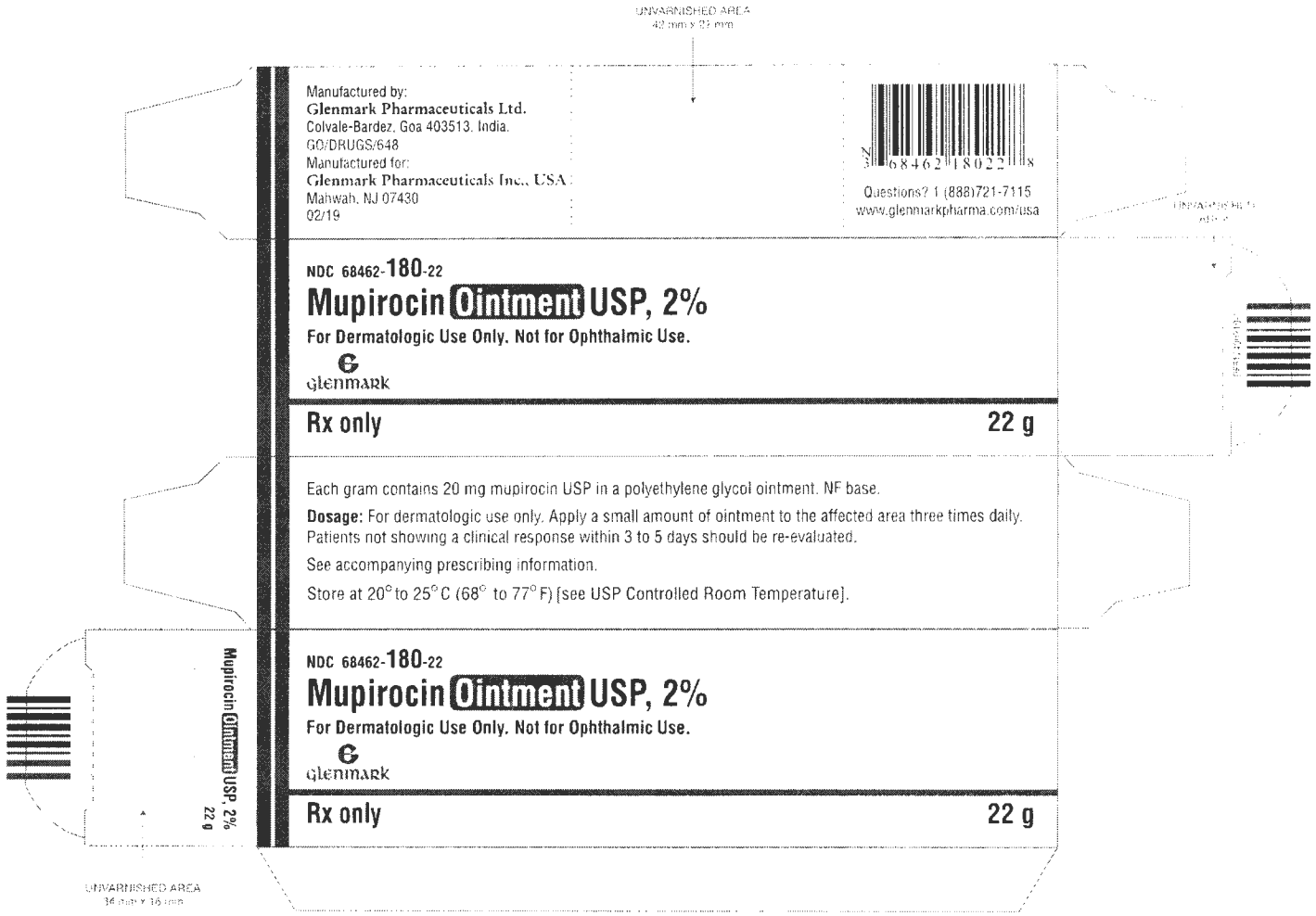
Please fax this form to: 1-817-868-5362 or E-mail rxrecalls@inmar.com

Market Withdrawal Event ID N131371 RCL249-25

Market Withdrawal Event ID N131371 RCL249-25

Reduction in Tube Length

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



Prathyusha Reddy Challa

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

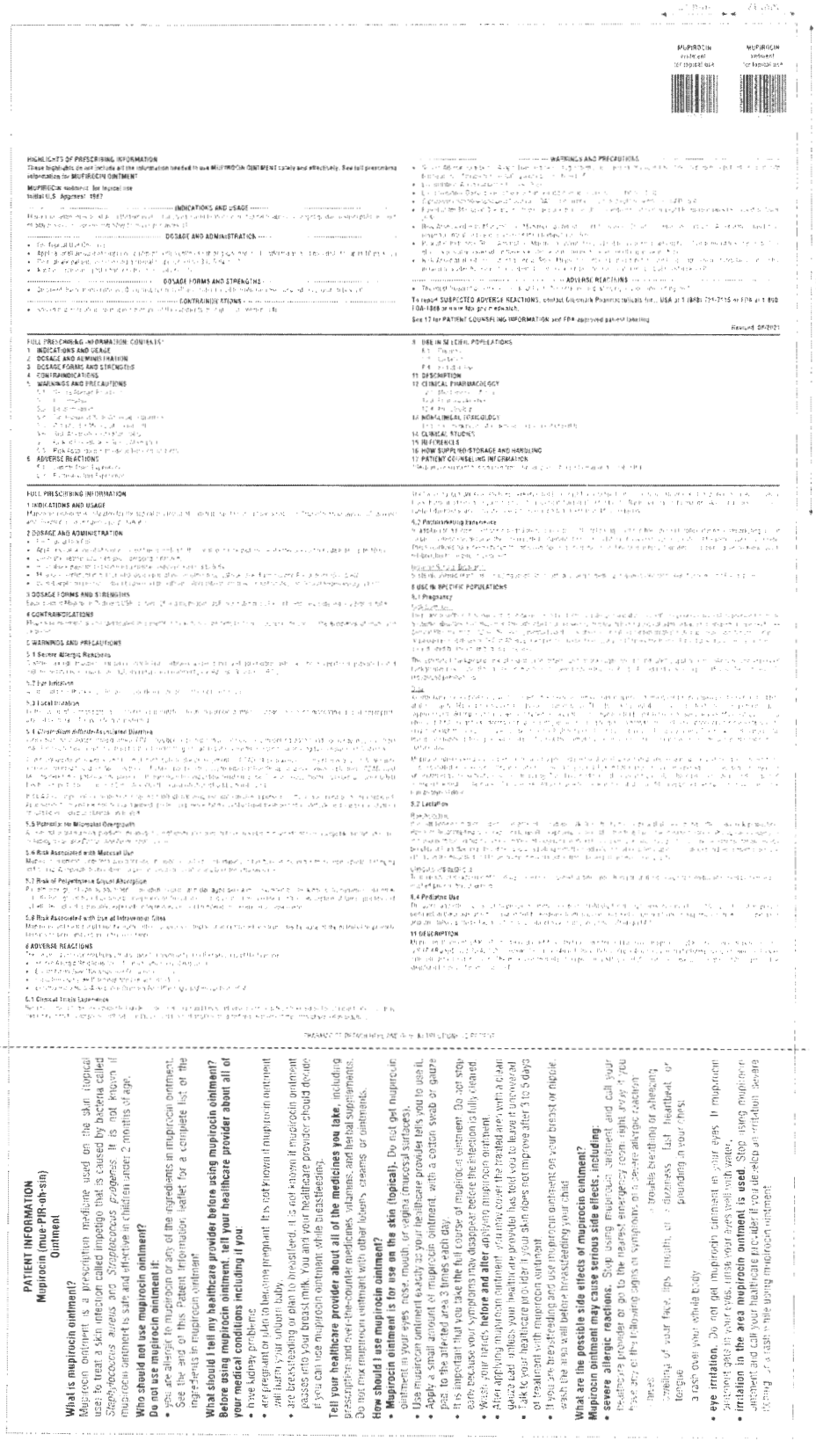
GLENMARK PHARMACEUTICALS LTD.			
PRODUCT NAME: Mupirocin Ointment	OATE:	PANTONE SHADE NO: BLACK 186 C 354 C	
ITEM CODE: PE51740 VERSION: 0219-1	PKG. DEV.:	Item code, Version, Consistency of Design, overprint area, Pack size, Dimensions & Layout	
PHARMACODE: 874	RA	Regulatory Text	
COUNTRY: USA	QA:	Entire Text	
LOCATION: COLVALE - GOA	PRODUCTION:	Machine Suitability	
PACK : CARTON - 22 g	REMARKS:		
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'



PATIENT INFORMATION
Mupirocin (mue-PIR-oh-sin)
Ointment

What is mupirocin ointment?
Mupirocin ointment is a prescription medicine used on the skin (topical) 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 mupirocin ointment?
Do not use mupirocin ointment if:
- you are allergic to mupirocin or any of the ingredients in mupirocin 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 ointment?
Before using mupirocin ointment, 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 ointment 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 ointment with other lotions, creams, or ointments.

How should I use mupirocin ointment?
- **Mupirocin ointment is for use on the skin (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 5 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 mupirocin ointment?
Mupirocin 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:
  - [illegible] of your face, lips, mouth, or throat
  - difficulty breathing or swallowing
  - dizziness, fast heartbeat, or pounding in your chest
  - a rash over your whole body
- **eye irritation.** 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 mupirocin ointment is used.** Stop using mupirocin ointment and call your healthcare provider if you develop an irritation, severe itching, or a rash while using mupirocin ointment.

GLENMARK PHARMACEUTICALS LTD.	DATE: 24-08-2021	PANTONE SHADE NO. BLACK	
PRODUCT NAME: MUPIROCIN OINTMENT 2% USP	PKG. DEV.:		Pradnya Kadam
ITEM CODE: PES5501 VERSION: 5501-1			
PHARMACODE: NA BARCODE: 55501	RA		
COUNTRY: USA	PRODUCTION:		
LOCATION: GNA	QA:		
PACK : [illegible]	REMARKS:		
ACTUAL SIZE: 240 x 400 mm			
SPECIFICATION: 28 GSM Bible Paper			
			FCPDC001/01.00

Webtech Industries

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

Carole Capella
Digitally signed by Carole Capella
Date: 2021.09.08 10:01:35 -04'00'

Kristin DiStefano
Digitally signed by Kristin DiStefano
Date: 2021.09.08 10:14:32 -04'00'

- **a type of diarrhea called *clostridium difficile*-associated 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 ointment.
- **risk of absorption of polyethylene glycol through the skin.** Mupirocin ointment contains polyethylene glycol, which in large amounts can cause kidney damage. You should not apply mupirocin ointment to open skin wounds or damaged skin, especially if you have kidney problems.
- **increased risk of infection at IV (intravenous) sites.** Mupirocin ointment 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
- itching

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 mupirocin ointment?

- Store mupirocin ointment at room temperature between 68°F to 77°F (20°C to 25°C).
- **Keep mupirocin ointment and all medicines out of the reach of children.**

General information about the safe and effective use of mupirocin ointment

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 mupirocin ointment?

Active Ingredient: mupirocin

Inactive Ingredients: polyethylene glycol 400 and polyethylene glycol 3350

Trademarks are the property of their respective owners.

Manufactured by:
Glenmark Pharmaceuticals Limited
Colvale-Bardez, Goa 403513, India

Manufactured for:

Glenmark Pharmaceuticals Inc., USA
Mahwah, NJ 07430

Questions? 1 (888) 721-7115
www.glenmarkpharma-us.com

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

GLENMARK PHARMACEUTICALS LTD.	DATE:	PANTONE SHADE NO. BLACK	
PRODUCT NAME:	PKG. DEV.:		Pradnya Kadam
ITEM CODE: VERSION:			
PHARMACODE: BARCODE:	RA		
COUNTRY:	PRODUCTION:		
LOCATION:	QA:		
PACK:	REMARKS:		
ACTUAL SIZE:			
SPECIFICATION:			FCPDC051/01.00

Webtech Industries

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

Carole Capella
Digitally signed by Carole Capella
Date: 2021.09.08 10:01:45 -04'00'

Kristin DiStefano
Digitally signed by Kristin DiStefano
Date: 2021.09.08 10:14:47 -04'00'