glenmark
A new way for a new world

URGENT: DRUG RECALL

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

September 13, 2024

Dear Customer,

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

Mupirocin Ointment USP, 2%

Sr. No.	NDC	Batch Number	Expiry Date
1.	68462-180-22	19224055	Sep-2024
2.	68462-180-22	19224281	Sep-2024
3.	68462-180-22	19224307	Sep-2024
4.	68462-180-22	19224321	Sep-2024
5.	68462-180-22	19224341	Sep-2024
6.	68462-180-22	19224467	Sep-2024
7.	68462-180-22	19224525	Oct-2024
8.	68462-180-22	19224542	Oct-2024
9.	68462-180-22	19224560	Oct-2024
10.	68462-180-22	19224580	Oct-2024
11.	68462-180-22	19224990	Nov-2024
12.	68462-180-22	19224998	Nov-2024
13.	68462-180-22	19225014	Nov-2024
14.	68462-180-22	19225033	Nov-2024
15.	68462-180-22	19225293	Nov-2024
16.	68462-180-22	19225304	Nov-2024
17.	68462-180-22	19225320	Nov-2024
18.	68462-180-22	19225349	Nov-2024
19.	68462-180-22	19225367	Nov-2024
20.	68462-180-22	19225379	Nov-2024
21.	68462-180-22	19225401	Nov-2024
22.	68462-180-22	19230115	Dec-2024
23.	68462-180-22	19230123	Dec-2024

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	Batch Number	Expiry Date
24.	68462-180-22	19230132	Dec-2024
25.	68462-180-22	19230137	Dec-2024
26.	68462-180-22	19230167	Dec-2024
27.	68462-180-22	19230170	Dec-2024
28.	68462-180-22	19230572	Jan-2025
29.	68462-180-22	19230607	Jan-2025
30.	68462-180-22	19230614	Jan-2025
31.	68462-180-22	19230628	Jan-2025
32.	68462-180-22	19230631	Jan-2025
33.	68462-180-22	19230874	Feb-2025
34.	68462-180-22	19230925	Feb-2025
35.	68462-180-22	19230941	Feb-2025
36.	68462-180-22	19230957	Feb-2025
37.	68462-180-22	19230976	Feb-2025
38.	68462-180-22	19231232	Feb-2025
39.	68462-180-22	19231238	Feb-2025
40.	68462-180-22	19231282	Feb-2025
41.	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 November 15th, 2022.

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

In addition, if you are a wholesaler/ distributor, who have further distributed this product, please identify those customers and notify them at once of this Product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter. This recall should be carried out to the retail level.

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.

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: 2024.09.13 10:12:06 -04'00'

Thomas Callaghan

Executive Director - Regulatory Affairs, North America

US Agent for Glenmark Pharmaceuticals Limited

Enclosure(s):

Product Labels

Recall 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

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	DATE:	PANTONE SHADE NO: BLACK 186 C 364 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'

21 mm
21 mm
150 mm
MUPIROCIN ointment, for topical use
MUPIROCIN ointment, for topical use

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use MUPIROCIN OINTMENT safely and effectively. See full prescribing information for MUPIROCIN OINTMENT.

MUPIROCIN ointment, for topical use
Initial U.S. Approval: 1987

INDICATIONS AND USAGE
Mupirocin ointment is an RNA synthetase inhibitor antibacterial indicated for the topical treatment of impetigo due to susceptible isolates of *Staphylococcus aureus* and *Streptococcus pyogenes*. (1)

DOSAGE AND ADMINISTRATION
- For Topical Use Only. (2)
- Apply a small amount of mupirocin ointment, with a cotton swab or gauze pad, to the affected area 3 times daily for up to 10 days. (2)
- Re-evaluate patients not showing a clinical response within 3 to 5 days. (2)
- Not for intranasal, ophthalmic, or other mucosal use. (2)

DOSAGE FORMS AND STRENGTHS
- Ointment: Each gram contains 20 mg mupirocin, USP in a water-miscible ointment base supplied in 22-gram tubes. (3)

CONTRAINDICATIONS
- Known hypersensitivity to mupirocin or any of the components of mupirocin ointment. (4)

WARNINGS AND PRECAUTIONS
- Severe Allergic Reactions: Anaphylaxis, urticaria, angioedema, and generalized rash have been reported in patients treated with formulations of mupirocin including mupirocin ointment. (5.1)
- Eye Irritation: Avoid contact with eyes. (5.2)
- Local Irritation: Discontinue in the event of sensitization or severe local irritation. (5.3)
- *Clostridium difficile*-Associated Diarrhea (CDAD): If diarrhea occurs, evaluate patients for CDAD. (5.4)
- Potential for Microbial Overgrowth: Prolonged use may result in overgrowth of nonsusceptible microorganisms, including fungi. (5.5)
- Risk Associated with Mucosal Use: Mupirocin ointment is not formulated for use on mucosal surfaces. A separate formulation, mupirocin nasal ointment, is available for intranasal use. (5.6)
- Risk of Polyethylene Glycol Absorption: Mupirocin ointment should not be used where absorption of large quantities of polyethylene glycol is possible, especially if there is evidence of moderate or severe renal impairment. (5.7)
- Risk Associated with Use at Intravenous Sites: Mupirocin ointment should not be used with intravenous cannulae or at central intravenous sites because of the potential to promote fungal infections and antimicrobial resistance. (5.8)

ADVERSE REACTIONS
- The most frequent adverse reactions (at least 1%) were burning, stinging or pain, and itching. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Glenmark Pharmaceuticals Inc., USA at 1 (888) 721-7115 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 09/2021

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE
Mupirocin ointment is indicated for the topical treatment of impetigo due to susceptible isolates of *Staphylococcus aureus (S. aureus)* and *Streptococcus pyogenes (S. pyogenes)*.

2 DOSAGE AND ADMINISTRATION
- For Topical Use Only.
- Apply a small amount of mupirocin ointment, with a cotton swab or gauze pad, to the affected area 3 times daily for up to 10 days.
- Cover the treated area with gauze dressing if desired.
- Re-evaluate patients not showing a clinical response within 3 to 5 days.
- Mupirocin ointment is not for intranasal, ophthalmic, or other mucosal use *[see Warnings and Precautions (5.2, 5.6)]*.
- Do not apply mupirocin ointment concurrently with pay other lotions, creams, or ointments *[see Clinical Pharmacology (12.3)]*.

3 DOSAGE FORMS AND STRENGTHS
Each gram of Mupirocin Ointment USP contains 20 mg mupirocin, USP in a water-miscible ointment base supplied in 22-gram tubes.

4 CONTRAINDICATIONS
Mupirocin ointment is contraindicated in patients with known hypersensitivity to mupirocin or any of the components of mupirocin ointment.

5 WARNINGS AND PRECAUTIONS

5.1 Severe Allergic Reactions
Systemic allergic reactions, including anaphylaxis, urticaria, angioedema, and generalized rash, have been reported in patients treated with formulations of mupirocin, including mupirocin ointment *[see Adverse Reactions (6.2)]*.

5.2 Eye Irritation
Avoid contact with the eyes. In case of accidental contact, rinse well with water.

5.3 Local Irritation
In the event of a sensitization or severe local irritation from mupirocin ointment, usage should be discontinued, and appropriate alternative therapy for the infection instituted.

5.4 *Clostridium difficile*-Associated Diarrhea
Clostridium difficile-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C. difficile*.

C. difficile produces toxins A and B which contribute to the development of CDAD. Hypertoxin-producing strains of *C. difficile* cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibacterial drug use. Careful medical history is necessary since CDAD has been reported to occur over 2 months after the administration of antibacterial agents.

If CDAD is suspected or confirmed, ongoing antibacterial drug use not directed against *C. difficile* may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibacterial treatment of *C. difficile*, and surgical evaluation should be instituted as clinically indicated.

5.5 Potential for Microbial Overgrowth
As with other antibacterial products, prolonged use of mupirocin ointment may result in overgrowth of nonsusceptible microorganisms, including fungi *[see Dosage and Administration (2)]*.

5.6 Risk Associated with Mucosal Use
Mupirocin ointment is not formulated for use on mucosal surfaces. Treatment use has been associated with isolated reports of stinging and drying. A separate formulation, mupirocin nasal ointment, is available for intranasal use.

5.7 Risk of Polyethylene Glycol Absorption
Polyethylene glycol can be absorbed from open wounds and damaged skin and is excreted by the kidneys. In common with other polyethylene glycol-based ointments, mupirocin ointment should not be used in conditions where absorption of large quantities of polyethylene glycol is possible, especially if there is evidence of moderate or severe renal impairment.

5.8 Risk Associated with Use at Intravenous Sites
Mupirocin ointment should not be used with intravenous cannulae or at central intravenous sites because of the potential to promote fungal infections and antimicrobial resistance.

6 ADVERSE REACTIONS
The following adverse reactions are discussed in more detail in other sections of the labeling:
- Severe Allergic Reactions *[see Warnings and Precautions (5.1)]*
- Eye Irritation *[see Warnings and Precautions (5.2)]*
- Local Irritation *[see Warnings and Precautions (5.3)]*
- *Clostridium difficile*-Associated Diarrhea *[see Warnings and Precautions (5.4)]*

6.1 Clinical Trials Experience
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared with rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The following local adverse reactions were reported by at least 1% of subjects in connection with the use of mupirocin ointment in clinical trials: burning, stinging, or pain in 1.5% of subjects; itching in 1% of subjects. Rash, nausea, erythema, dry skin, tenderness, swelling, contact dermatitis, and increased exudate were reported in less than 1% of subjects.

6.2 Postmarketing Experience
In addition to adverse reactions reported from clinical trials, the following reactions have been identified during postmarketing use of mupirocin ointment. Because they are reported voluntarily from a population of unknown size, estimates of frequency cannot be made. These reactions have been chosen for inclusion due to a combination of their seriousness, frequency of reporting, or potential causal relationship to mupirocin ointment.

Immune System Disorders
Systemic allergic reactions, including anaphylaxis, urticaria, angioedema, and generalized rash *[see Warnings and Precautions (5.1)]*.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary
There are insufficient human data to establish whether there is a drug-associated risk with mupirocin ointment in pregnant women. Systemic absorption of mupirocin through intact human skin is minimal following topical administration of mupirocin ointment *[see Clinical Pharmacology (12.3)]*. No developmental toxicity was observed in rats or rabbits treated with mupirocin subcutaneously during organogenesis at doses of 180 or 40 mg per kg per day, respectively (20 and 11 times the human topical dose based on calculations of dose divided by the entire body surface area).

The estimated background risk of major birth defects and miscarriages for the indicated population is unknown. The estimated background risk in the U.S. general population of major birth defects is 2% to 4% and of miscarriage is 15% to 20% of clinically recognized pregnancies.

Data
Animal Data: Developmental toxicity studies have been performed with mupirocin administered subcutaneously to rats and rabbits at doses up to 180 mg per kg per day during organogenesis. This dose is 22 and 43 times, respectively, the human topical dose (approximately 60 mg mupirocin per day) based on calculations of dose divided by the entire body surface area. Maternal toxicity was observed (body weight loss/decreased body weight gain and reduced feeding) in both species with an evidence of developmental toxicity in rats. In rabbits, excessive maternal toxicity at the high dose precluded the evaluation of fetal outcomes. There was no developmental toxicity in rabbits at 40 mg per kg per day, 11 times the human topical dose based on calculations of dose divided by the entire body surface area.

Mupirocin administered subcutaneously to rats in a pre-and postnatal development study (dosed during late gestation through lactation) was associated with reduced offspring viability in the early postnatal period at a dose of 108.7 mg per kg, in the presence of injection site irritation and/or subcutaneous hemorrhaging. This dose is 14 times the human topical dose based on calculations of dose divided by the entire body surface area. The no-observed adverse effect level in this study was 44.2 mg per kg per day, which is 6 times the human topical dose.

8.2 Lactation

Risk Summary
It is not known whether mupirocin is present in human milk, has effects on the breastfed child, or has effects on milk production. However, breastfeeding is not expected to result in exposure of the child to the drug due to the minimal systemic absorption of mupirocin in humans following topical administration of mupirocin ointment *[see Clinical Pharmacology (12.3)]*. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for mupirocin ointment and any potential adverse effects on the breastfed child from mupirocin ointment or from the underlying maternal condition.

Clinical Considerations
To minimize oral exposure of the drug to children, a breast and/or nipple being treated with mupirocin ointment should be thoroughly washed prior to breastfeeding.

8.4 Pediatric Use
The safety and effectiveness of mupirocin ointment have been established in the age range of 2 months to 16 years. Use of mupirocin ointment in these age groups is supported by evidence from adequate and well-controlled trials of mupirocin ointment in impetigo in pediatric subjects studied as a part of the pivotal clinical trials *[see Clinical Studies (14)]*.

11 DESCRIPTION
Mupirocin Ointment USP, 2% contains the RNA synthetase inhibitor antibacterial, mupirocin, USP. The chemical name is (*E*)-(2*S*,3*R*,4*R*,5*S*)-5-[(2*S*,3*S*,4*S*,5*S*)-2,3-epoxy-5-hydroxy-4-methylhexyl]tetrahydro-3,4-dihydroxy-β-methyl-2*H*-pyran-2-crotonic acid, ester with 9-hydroxynonanoic acid. The molecular formula of mupirocin, USP is $C_{26}H_{44}O_9$, and the molecular weight is 500.6 g/mol. The structural formula of mupirocin, USP is:

PHARMACIST: DETACH HERE AND GIVE INSTRUCTIONS TO PATIENT

Printed Perforation

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

What is mupirocin ointment?
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 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 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 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:
  - hives
  - swelling of your face, lips, mouth, or tongue
  - trouble breathing or wheezing
  - 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% US LF	**PKG. DEV.:**	Item code, Version, Consistency of Design, overprint area, Pack size, Dimensions & Layout	Pradnya Kadam
ITEM CODE: PE56801 **VERSION:** 0821-1			
PHARMACODE: NA **BARCODE:** 56801	**RA**	Regulatory Text	
COUNTRY: USA	**PRODUCTION:**	Machine Suitability	
LOCATION: GDA	**QA:**	Entire Text	Vikram Dasal (0900)39468 Sr. Officer QA
PACK : 21 x 150 mm			
ACTUAL SIZE: 240 x 430 mm	**REMARKS:**		
SPECIFICATION: 28 GSM Bible Paper			FCPDC001/01.00

Webtech Industries Font: Helvetica Condensed. Size: 6 pt. & 10 pt.

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'

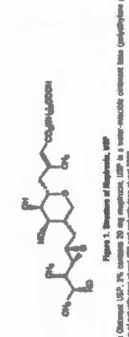

Figure 1. Structure of Mupirocin, USP

PE56801 0821-1

PHARMACIST-DETACH HERE AND GIVE INSTRUCTIONS TO PATIENT

- **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

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

Printed Perforation

GLENMARK PHARMACEUTICALS LTD	DATE: 24-08-2021	PANTONE SHADE NO: BLACK	
PRODUCT NAME: MUPIROCIN OINTMENT 2% US LF	PKG. DEV.:	Item code, Version, Consistency of Design: overprint area, Pack size, Dimensions & Layout	Pradnya Kadam
ITEM CODE: PE56801 VERSION: 0821-1			
PHARMACODE: NA BARCODE: 56801	RA	Regulatory Text	
COUNTRY: USA	PRODUCTION:	Machine Suitability	
LOCATION: GOA	QA:	Entire Text	Vikram Desai
PACK: 21 x 150 mm	REMARKS:		
ACTUAL SIZE: 240 x 430 mm			
SPECIFICATION: 28 GSM Bible Paper			
		FCPDC001/01.00	

Webtech Industries Font: Helvetica Condensed. Size: 8 pt. & 10 pt.

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'

Glenmark
A new way for a new world

Glenmark Pharmaceuticals Inc.
RECALL RETURN RESPONSE FORM
MUPIROCIN OINTMENT USP, 2% 22 g Tube pack
NDC 68462-180-22
Retail Level
09/13/2024

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#:	
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 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	19224055	Sep-2024	
2.	MUPIROCIN OINTMENT USP 2%	68462-180-22	19224281	Sep-2024	
3.	MUPIROCIN OINTMENT USP 2%	68462-180-22	19224307	Sep-2024	
4.	MUPIROCIN OINTMENT USP 2%	68462-180-22	19224321	Sep-2024	
5.	MUPIROCIN OINTMENT USP 2%	68462-180-22	19224341	Sep-2024	
6.	MUPIROCIN OINTMENT USP 2%	68462-180-22	19224467	Sep-2024	

Sr. No.	Item Description	NDC#	Lot#	Exp. Date	Total Full/Sealed and Partial/Open Tube Count
7.	MUPIROCIN OINTMENT USP 2%	68462-180-22	19224525	Oct-2024	
8.	MUPIROCIN OINTMENT USP 2%	68462-180-22	19224542	Oct-2024	
9.	MUPIROCIN OINTMENT USP 2%	68462-180-22	19224560	Oct-2024	
10.	MUPIROCIN OINTMENT USP 2%	68462-180-22	19224580	Oct-2024	
11.	MUPIROCIN OINTMENT USP 2%	68462-180-22	19224990	Nov-2024	
12.	MUPIROCIN OINTMENT USP 2%	68462-180-22	19224998	Nov-2024	
13.	MUPIROCIN OINTMENT USP 2%	68462-180-22	19225014	Nov-2024	
14.	MUPIROCIN OINTMENT USP 2%	68462-180-22	19225033	Nov-2024	
15.	MUPIROCIN OINTMENT USP 2%	68462-180-22	19225293	Nov-2024	
16.	MUPIROCIN OINTMENT USP 2%	68462-180-22	19225304	Nov-2024	
17.	MUPIROCIN OINTMENT USP 2%	68462-180-22	19225320	Nov-2024	
18.	MUPIROCIN OINTMENT USP 2%	68462-180-22	19225349	Nov-2024	
19.	MUPIROCIN OINTMENT USP 2%	68462-180-22	19225367	Nov-2024	
20.	MUPIROCIN OINTMENT USP 2%	68462-180-22	19225379	Nov-2024	
21.	MUPIROCIN OINTMENT USP 2%	68462-180-22	19225401	Nov-2024	
22.	MUPIROCIN OINTMENT USP 2%	68462-180-22	19230115	Dec-2024	
23.	MUPIROCIN OINTMENT USP 2%	68462-180-22	19230123	Dec-2024	
24.	MUPIROCIN OINTMENT USP 2%	68462-180-22	19230132	Dec-2024	
25.	MUPIROCIN OINTMENT USP 2%	68462-180-22	19230137	Dec-2024	
26.	MUPIROCIN OINTMENT USP 2%	68462-180-22	19230167	Dec-2024	
27.	MUPIROCIN OINTMENT USP 2%	68462-180-22	19230170	Dec-2024	
28.	MUPIROCIN OINTMENT USP 2%	68462-180-22	19230572	Jan-2025	
29.	MUPIROCIN OINTMENT USP 2%	68462-180-22	19230607	Jan-2025	
30.	MUPIROCIN OINTMENT USP 2%	68462-180-22	19230614	Jan-2025	
31.	MUPIROCIN OINTMENT USP 2%	68462-180-22	19230628	Jan-2025	
32.	MUPIROCIN OINTMENT USP 2%	68462-180-22	19230631	Jan-2025	
33.	MUPIROCIN OINTMENT USP 2%	68462-180-22	19230874	Feb-2025	
34.	MUPIROCIN OINTMENT USP 2%	68462-180-22	19230925	Feb-2025	
35.	MUPIROCIN OINTMENT USP 2%	68462-180-22	19230941	Feb-2025	
36.	MUPIROCIN OINTMENT USP 2%	68462-180-22	19230957	Feb-2025	
37.	MUPIROCIN OINTMENT USP 2%	68462-180-22	19230976	Feb-2025	
38.	MUPIROCIN OINTMENT USP 2%	68462-180-22	19231232	Feb-2025	
39.	MUPIROCIN OINTMENT USP 2%	68462-180-22	19231238	Feb-2025	
40.	MUPIROCIN OINTMENT USP 2%	68462-180-22	19231282	Feb-2025	
41.	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
Recall Event ID RCL221-24 / N131208