

Mupirocin Ointment USP, 2%

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Mupirocin Ointment USP, 2% 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 any other lotions, creams, or ointments [see Clinical Pharmacology (12.3)].

3 DOSAGE FORMS AND STRENGTHS

Each gram of mupirocin ointment contains 20 mg mupirocin in a water-miscible ointment base supplied in 15-gram, 22-gram and 30-gram tubes.

4 CONTRAINDICATIONS

Mupirocin ointment is contraindicated in patients with known hypersensitivity to mupirocin or any of the excipients 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. Intranasal use has been associated with isolated reports of stinging and drying. A separate formulation, mupirocin calcium 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.

- 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 Taro Pharmaceuticals U.S.A., Inc., at 1-866-923-4914 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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

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

MUPIROICIN 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 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 in a water-miscible ointment base supplied in 15-gram, 22-gram and 30-gram tubes. (3)

CONTRAINDICATIONS

- Known hypersensitivity to mupirocin or any of the excipients 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)

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PHARMACIST-DETACH HERE AND GIVE INSTRUCTIONS TO PATIENT

PATIENT INFORMATION MUPIROICIN (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:

o hives

o swelling of your face, lips, mouth, or tongue

o a rash over your whole body

o trouble breathing or wheezing

o dizziness, fast heartbeat, or pounding in your chest

