MUPIROCIN

Category

Antibacterial (topical).

Indications

Note: Bracketed information in the Indications section refers to uses that are not included in U.S. product labeling.

Accepted

Impetigo (treatment)¾Mupirocin is indicated [alone as a primary agent] 7 in the topical treatment of [localized] 7 impetigo caused by Staphylococcus aureus and beta-hemolytic streptococci, including Streptococcus pyogenes. 1, 2, 3, 4, 5

[However, some USP medical experts prefer systemic antibacterials in the treatment of most cases of impetigo.] 7

[Eczema, infected (treatment)] or

[Folliculitis (treatment)] *¾Mupirocin is used as a primary agent 7 in the topical treatment of localized 7 infected eczema 2, 3 and folliculitis 2, 3 caused by S. aureus. 2, 3, 5

[Skin infections, bacterial, minor (prophylaxis)]¾Mupirocin is used in the topical prophylaxis of minor bacterial skin infections. 2, 5

Skin lesions, secondarily infected, traumatic (treatment)¾Mupirocin is indicated for the treatment of secondarily infected traumatic skin lesions (up to 10 cm in length or 100 cm2in area) due to susceptible strains of Staphylococcus aureusand Streptococcus pyogenes. 12

Not all species or strains of a particular organism may be susceptible to mupirocin.

Unaccepted

Mupirocin is not effective against Enterobacteriaceae , Pseudomonas aeruginosa , or fungi. 4

* Not included in Canadian product labeling.

Pharmacology/Pharmacokinetics

Physicochemical characteristics:

Source¾Produced by fermentation of Pseudomonas fluorescens

Chemical group¾Structurally unrelated to other systemic or topical antibacterials 2, 3.

Molecular weight¾500.63

Mechanism of action/Effect:

The mechanism of action is not completely understood. Mupirocin is bacteriostatic at low concentrations and bactericidal at high concentrations. This agent reversibly and specifically binds to bacterial isoleucyl transfer RNA synthetase, thereby inhibiting bacterial protein and RNA synthesis. DNA synthesis and cell wall formation are affected to a lesser extent. 1, 2, 3, 4, 5

Absorption:

Virtually no systemic absorption (< 1.1 nanograms per mL of whole blood) following application to lower arm of normal males with occlusion for 24 hours. 1

Precautions to Consider

Pregnancy/Reproduction

Fertility¾Adequate and well-controlled studies in humans have not been done.

Studies in rats and rabbits given oral, subcutaneous, and intramuscular doses of up to 100 times the human topical dose, have not shown that mupirocin causes impaired fertility. 1

Pregnancy¾Adequate and well-controlled studies in humans have not been done.

Studies in rats and rabbits given oral, subcutaneous, and intramuscular doses of up to 100 times the human topical dose, have not shown that mupirocin causes adverse effects in the fetus. 1

FDA Pregnancy Category B.

Breast-feeding

It is not known whether mupirocin is distributed into breast milk. However, problems in humans have not been documented. Mupirocin is unlikely to be distributed into breast milk in significant amounts since virtually no systemic absorption occurs following topical administration. 1

Pediatrics

The safety and effectiveness of Bactroban Creamhave been established in the age groups 3 months to 16 years. 12

Geriatrics

In two studies, 30 patients over 65 years old were treated with Bactroban Cream and no overall difference in the efficacy or safety was observed. 12

Medical considerations/Contraindications

The medical considerations/contraindications included have been selected on the basis of their potential clinical significance (reasons given in parentheses where appropriate)¾ not necessarily inclusive (>> = major clinical significance).

Risk-benefit should be considered when the following medical problem exists

Sensitivity to mupirocin

Side/Adverse Effects

Note: The polyethylene glycol vehicle in mupirocin ointment may irritate broken skin or mucous membranes. 4

When mupirocin ointment is applied to extensive open wounds or burns, the possibility of absorption of the polyethylene glycol vehicle, resulting in serious renal toxicity, should be considered. 4

Mupirocin ointment has not been reported to cause contact sensitization or photosensitivity reactions. 2, 3, 4

The following side/adverse effects have been selected on the basis of their potential clinical significance (possible signs and symptoms in parentheses where appropriate)¾not necessarily inclusive:

Those indicating need for medical attention only if they continue or are bothersome

Incidence less frequent

Dry skin 1, 2, 5; skin burning, itching, pain, rash, redness, stinging, or swelling 1, 2, 3, 4, 5; headache 12; nausea 12, 12

Incidence rare

Abdominal pain 12; dizziness 12; secondary wound infection 12; ulcerative stomatitis (sores in mouth or on lips) 12

Patient Consultation

As an aid to patient consultation, refer to Advice for the Patient, Mupirocin (Topical) .

In providing consultation, consider emphasizing the following selected information (>> = major clinical significance):

Proper use of this medication

>> Not for ophthalmic use

To use

Before applying, washing affected area(s) with soap and water and drying thoroughly; applying small amount and rubbing in gently

After applying, covering treated area(s) with gauze dressing if desired

>> Compliance with full course of therapy

>> Proper dosing

Missed dose: Applying as soon as possible; not applying if almost time for next dose

>> Proper storage

Precautions while using this medication

Checking with physician or pharmacist if no improvement within 3 to 5 days

General Dosing Information

Topical mupirocin is not for ophthalmic use. 1, 5

The treated area(s) may be covered with a gauze dressing if desired. 1, 5

When mupirocin ointment is applied to extensive open wounds or burns, the possibility of absorption of the polyethylene glycol vehicle, resulting in serious renal toxicity, should be considered. 4

If skin irritation or hypersensitivity develops, treatment with mupirocin ointment should be discontinued. 1

Topical Dosage Forms

Note: Bracketed uses in the Dosage Forms section refer to categories of use and/or indications that are not included in U.S. product labeling.

MUPIROCIN OINTMENT 9 USP

Usual adult and adolescent dose

Impetigo or

[Eczema, infected]or

[Folliculitis] *¾

Topical, to the affected area(s), three times a day. 1, 2, 3, 4, 5, 7

Usual pediatric dose

See Usual adult and adolescent dose.

Strength(s) usually available

U.S.¾2% (Rx)[Bactroban (polyethylene glycol [PEG] 400) (PEG 3350)] 10

Canada¾2% (OTC)[Bactroban (polyethylene glycol [PEG] 400) (PEG 3350)] 8, 11

Packaging and storage:

Store between 15 and 30 °C (59 and 86 °F), in a well-closed container, unless otherwise specified by manufacturer. Protect from freezing.

Auxiliary labeling:

· For external use only.

· Continue medicine for full time of treatment.

Note: Mupirocin ointment is available in a bland, water-miscible ointment base.

MUPIROCIN CALCIUM CREAM 2%

Usual adult and adolescent dose

Secondarily infected traumatic skin lesion ¾

Topical, the affected area(s), three times a day for 10 days. 12

Usual pediatric dose

SeeUsual adult and adolescent dose

Strength(s) usually available

U.S.¾2% (Rx)[Bactroban (benzyl alcohol) (cetomacrogol 1000) (cetyl alcohol) (mineral oil) (phenoxyethanol) (purified water) (stearyl alcohol) (xanthan gum)] 12

Packaging and storage:

Store at or below 25° C (77° F). Protect from freezing

Auxiliary labeling:

· For external use only.

· Continue medicine for full time of treatment.

Note: Mupirocin cream is available in an oil and water-based emulsion.