Mupirocin

Bactifree®

Trusted Quality Healthcare

20 mg/g (2%) Ointment
Topical Antibacterial

FORMULATION
Each gram ointment contains:
Mupirocin ..... 20 mg/g (2%)

PRODUCT DESCRIPTION
Mupirocin ointment is a colorless, viscous ointment with faint characteristic odor.

WHAT IS IN THE MEDICINE?
This medicine contains mupirocin, a topical antibacterial that helps heal minor cuts and wounds in the skin and is used to treat or prevent skin infections caused by *Staphylococcus aureus* and *Streptococcus pyogenes*.

STRENGTH OF THE MEDICINE
See Formulation.

WHAT IS THIS MEDICINE USED FOR?
- For the treatment of primary bacterial skin infections such as impetigo (contagious, pus-containing skin disease), folliculitis (the inflammation of hair follicles), furunculosis (painful skin boil) and ecthyma (similar to impetigo occurring in the deep skin layers).
- For the treatment of bacterial infections secondary to skin conditions such as eczema (any inflammatory skin conditions accompanied by itching), psoriasis (reddish, scaly skin rash), atopic dermatitis (recurrent skin inflammation associated with allergies), herpes (tiny blisters on the skin caused by the herpes virus), epidermolysis bullosa (loosening of the epidermis with blister formation), and ichthyosis (noninflammatory scaling of the skin).
- Used in insect bites and in infected minor traumatic lesions such as skin ulcers, burns, cuts, abrasions (area where skin or tissue is scraped away), small lacerations (torn skin), sutured wounds, biopsy sites, surgical incisions).
- Used to prevent bacterial contamination in minor burns, biopsy sites, incisions and other clean lesions.
- Used to prevent the development of infection and permit wound healing in abrasions, minor cuts and wounds.

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?
Wash hands before and after each application unless mupirocin is used to treat a hand condition.
- Clean the affected and adjacent area with mild soap and water.
- Rinse thoroughly and pat dry.
- Apply a small amount of mupirocin ointment or cream on the affected area three times daily for up to 10 days, or as recommended by a doctor. The treated area may be covered with gauze dressing if needed.
- Re-assess patients not showing a clinical response within 3 to 5 days.
- Do not mix mupirocin with other lotions, creams or ointments on the infected area of the skin as this may reduce the effectiveness and stability of mupirocin.

WHEN SHOULD YOU NOT USE THIS MEDICINE?
- If you are allergic to mupirocin or to any ingredient of the product.
- **DO NOT apply** on the eyes or inside the nose.

UNDESIRABLE EFFECTS
Mupirocin is usually well tolerated when applied to the skin. Most of its adverse effects are mild, local and transient. The most common adverse effects of mupirocin are burning sensation, stinging, pain, itching, swelling, redness and rash.

Infections and infestations: Cellulitis (inflammation of connective tissue), pharyngitis (sore throat), secondary wound infection, upper respiratory tract infection
Immune system disorders: Angioedema (swelling of the face, lips, mouth, tongue or throat which may cause difficulty in breathing and swallowing), application site hypersensitivity reactions, systemic allergic reactions
Nervous system disorders: Dizziness, headache
Gastrointestinal disorders: Abdominal pain, diarrhea, nausea, ulcerative stomatitis (sores in the mouth or tongue)
Skin and subcutaneous tissue disorders: Contact dermatitis (skin inflammation caused by materials or substances in contact with the skin), cutaneous sensitization reactions (allergic skin reactions to mupirocin or the ointment base), exfoliative dermatitis (redness and peeling of the skin over large areas of the body), furunculosis, hives (raised, itchy rashes), skin dryness
General disorders and administration site conditions: Fever, increased exudates, injury, pain or bleeding secondary to eczema, tenderness

WHAT OTHER MEDICINE OR FOOD SHOULD BE AVOIDED WHILE USING THIS MEDICINE?
- Hydrocortisone, phenol, sulfur, or triamcinolone acetonide is compatible with mupirocin 2% ointment for at least 28 days at room temperature when extemporaneously admixed with the ointment to provide concentrations of these drugs of 1, 3, 2, or 0.1%, respectively. However, the stability of admixtures of mupirocin ointment and *commercially available* topical formulations of these drugs has not been established.
- Mupirocin 2% ointment is incompatible with salicylic acid 2%.
- Mupirocin should not be mixed with water-containing vehicles or formulations such as Aquaphor® or coal tar solution.

WHAT SHOULD YOU DO IF YOU MISS A DOSE?
If you miss a dose, just apply the next dose if still needed for the condition being treated and the following doses at the recommended time or schedule. If your next dose is due within an hour, do not apply the missed dose.

Do not use a double dose to make up for a missed dose.

SIGNS AND SYMPTOMS OF OVERDOSAGE
The toxicity of mupirocin is very low. Because of the possible side effects of polyethylene glycol, kidney function of patients with renal insufficiency should be closely monitored.

WHAT TO DO WHEN YOU HAVE USED MORE THAN THE RECOMMENDED DOSAGE?
If you have used more than the recommended dosage, consult the doctor immediately for advice.

CARE THAT SHOULD BE TAKEN WHEN USING THIS MEDICINE
- For external use on the skin only.
- Avoid contact with the eyes. If the ointment or cream comes in contact with the eyes, rinse out promptly and thoroughly with water.
- Do not use at the site of central venous cannulation.
- As with other polyethylene glycol-based ointments, do not use mupirocin ointment in conditions where large amounts of polyethylene glycol may be absorbed (e.g., in open wounds, extensive burns, broken skin), particularly in patients with moderate or severe renal impairment.
- In cases of sensitivity or severe local irritation, discontinue mupirocin treatment and consult a doctor.
- As with other antibacterial products, long-term use may result in overgrowth of non-susceptible organisms, including fungi.
- Do not use more than the recommended dose.
- Do not use after the expiry date on the label.

WHEN SHOULD YOU CONSULT YOUR DOCTOR?
Consult your doctor before using this medicine if you:
- Are pregnant or breastfeeding

Stop using this product and contact a doctor immediately if:
- Symptoms do not improve or new symptoms appear within three to five days
- You had pseudomembranous colitis characterized by diarrhea with blood and mucus, stomach pain and fever due to an inflamed colon
- You had signs of severe skin reactions or allergies such as:
  - Raised and itchy rash
  - Swelling of the face or mouth, resulting to difficulty in breathing and wheezing (to breathe making a whistling, high-pitched sound)
  - Dizziness, fast hearbeat, or pounding in your chest
  - Collapse or loss of consciousness

ADVERSE DRUG REACTION REPORTING STATEMENT
For suspected adverse drug reaction, seek medical attention immediately and report to the FDA at www.fda.gov.ph AND Unilab at (+632) 858-1000 or productsafety@unilab.com.ph. By reporting undesirable effects, you can help provide more information on the safety of this medicine.

HOW SHOULD YOU KEEP THIS MEDICINE?
Keep container tightly closed.
Store at temperatures not exceeding 25°C. Do not freeze.
Keep the product out of sight and reach of children.

AVAILABILITY
Mupirocin (BACTIFREE®) Ointment in Collapsible Aluminum tube of 5 g and 10 g.

DATE OF REVISION OF PATIENT INFORMATION LEAFLET (PIL): October 2018

DATE OF FIRST AUTHORIZATION: June 2007

Manufactured by:
AMHERST LABORATORIES, INC.
UNILAB Pharma Campus, Barangay Mamplasan
Biñan, Laguna, Philippines
For:
UNILAB, Inc.
No. 66 United Street, Mandaluyong City
Metro Manila, Philippines

Reg. IPOPHIL DRP-1138 P300000023725