

170mm

119mm

STORAGE CONDITIONS, USER INSTRUCTIONS AND PHARMACEUTICAL PRECAUTIONS:

Store below 30°C, in a well closed container. Protect from freezing. Any ointment remaining at the end of treatment should be discarded.

Auxiliary Labelling

- For external use only
- Continue medicine for full time of treatment.

PACKING / PACK SIZES:

Collapsible aluminium tube of 5g and 15g/box

SHELF LIFE: 3 years**MANUFACTURER AND PRODUCT REGISTRATION HOLDER:**

SM Pharmaceuticals Sdn Bhd (218620-M)
Lot 88, Sungai Petani Industrial Estate
08000 Sungai Petani
Kedah Darul Aman,
Malaysia.

19.11.2024

SM PHARMACEUTICALS SDN BHD**BACTRICIN (MUPIROCIN) OINTMENT 2%****DESCRIPTION:**

A cream to light yellowish, smooth, semi solid mass.

COMPOSITION:

Each gram contains: Mupirocin 20 mg (2%)

ACTIONS AND MODE OR MECHANISMS OF ACTION:

Actions: Mupirocin is mainly active against Gram-positive aerobes. Most strains of staphylococci (including methicillin-resistant and multiply-resistant *Staph. aureus*) and streptococci are susceptible *in vitro*. Mupirocin is also active against *Listeria monocytogenes* and *Erysipelothrix rhusiopathiae*. The Gram-negative organisms are generally insensitive, but *Haemophilus influenzae*, *Neisseria spp.* and few others are sensitive. Anaerobic organisms, both Gram-positive and Gram-negative, are generally resistant and activity against fungi is low. The antibiotic has an 8000-fold greater inhibitory effect on the enzyme of *Escherichia coli* B than on that of rat liver.

Mechanisms of action: 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.



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PHARMACOLOGY (SUMMARY OF PHARMACODYNAMICS AND PHARMACOKINETICS):

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.

Metabolism and Excretion: Systemically absorbed Bactricin is rapidly metabolised to the inactive metabolite monic acid and quickly excreted by the kidneys.

INDICATION:

Treatment of bacterial skin infections, e.g. impetigo, folliculitis and furunculosis.

CONTRAINDICATIONS:

Hypersensitivity to mupirocin or polyethylene glycol.

SIDE EFFECTS / ADVERSE REACTIONS:

Mupirocin is usually well tolerated but local reactions such as burning, stinging, itching, erythema and dryness may occur after the application of mupirocin to the skin.

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

PRECAUTIONS / WARNINGS:

Not suitable for ophthalmic or intranasal use. When use on the face, care should be taken to avoid the eyes. Polyethylene glycol can be absorbed from open wounds and damaged skin and is secreted by the kidneys. Care is also required in patients with renal impairment.

Use in pregnancy

Animal studies do not show any evidence of teratogenicity. However, there is inadequate evidence of safety to recommend the use of Bactricin during pregnancy.

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.

DRUG INTERACTIONS:

There are no available data on this subject.

RECOMMENDED DOSAGE, DOSAGE SCHEDULE AND ROUTE OF ADMINISTRATION:

It should be applied up to three times a day for up to 10 days. This ointment is not suitable for application to mucous membranes.

SYMPTOMS AND TREATMENT FOR OVERDOSAGE, AND ANTIDOTE(S):

The toxicity of mupirocin is very low. In the event of overdose, symptomatic treatment should be given.

