140.00 mm

TEXT MATTER FONT SIZE:- 7PT

FRONT

1. NAME OF MEDICINAL PRODUCT

BACOREN Mupirocin Ointment BP 2.0 % w/w

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g of ointment contains 20 mg Mupirocin BP

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Ointment for topical application.

White to off-white ointment, homogenous & free of agglomerates.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Mupirocin ointment is used for bacterial skin infections, e.g., impetigo, folliculitis, furunculosis.

4.2 Posology and Method of Administration

Route of Administration: Topical

Adults & Children

BACOREN should be applied to the affected area 2 to 3 times a day for up to 10 days, depending on the response. The area may be covered with a dressing or occluded if desired. Do not mix with other preparations as there is a risk of dilution, resulting in a reduction of the antibacterial activity and potential loss of stability of the mupirocin in the ointment.

4.3 Contraindications

BACOREN should not be given to patients with a history of hypersensitivity to any of its constituents. This ointment formulation is not suitable for ophthalmic or intranasal use.

4.4 Special Warnings and Precautions for Use

Should a possible sensitisation reaction or severe local irritation occur with the use of mupirocin ointment, treatment should be discontinued, the product should be washed off and appropriate therapy instituted.

As with other antibacterial products, prolonged use may result in overgrowth of non-susceptible organisms. Pseudomembranous colitis has been reported with the use of antibiotics and may range in severity from mild to life-threatening. Therefore, it is important to consider its diagnosis in patients who develop diarrhoea during or after antibiotic use. Although this is less likely to occur with topically applied mupirocin, if prolonged or significant diarrhoea occurs or the patient experiences abdominal cramps, treatment should be discontinued immediately, and the patient investigated further.

Renal Impairment

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.

Mupirocin ointment is not suitable for:

- Ophthalmic use
- Intranasal use
- Use in conjunction with cannula
- At the site of central venous cannulation

Avoid contact with the eyes. If contaminated, the eyes should be thoroughly irrigated with water until the ointment residues have been removed.

4.5 Interaction with Other Medicinal Products and Other Forms of Interaction

Not known

4.6 Fertility, Pregnancy and Lactation

Pregnancy: Reproduction studies on mupirocin in animals have revealed no evidence of harm to the foetus. As there is no clinical experience on its use during pregnancy, mupirocin ointment should only be used in pregnancy when the potential benefits outweigh the possible risks of treatment.

Lactation: There is no information on the excretion of mupirocin in milk. If a cracked nipple is to be treated, it should be thoroughly washed prior to breast feeding.

Fertility: There are no data on the effects of mupirocin on human fertility. Studies in rats showed no effects on fertility.

4.7 Effects on Ability to Drive and Use Machines

BACOREN has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable Effects

Immune system disorders

Very rare: Systemic allergic reactions including anaphylaxis, generalized rash, urticaria and angioedema have been reported with mupirocin ointment.

Skin and subcutaneous tissue disorders

Common: Burning localised to the area of application.

Uncommon: Itching, erythema, stinging and dryness localised to the area of application.

Cutaneous sensitisation reactions to mupirocin or the ointment base.

4.9 Overdose

Symptoms and signs

There is currently limited experience with overdosage of mupirocin.

Treatment

There is no specific treatment for an overdose of Mupirocin. In the event of overdose, the patient should be treated supportively with appropriate monitoring as necessary. Further management should be as clinically indicated or as recommended by the national poisons centre, where available.

BACK

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: Antibiotics and chemotherapeutics for dermatological use. ATC code: D06AX09

Mode of action

Mupirocin is a novel antibiotic produced through fermentation by *Pseudomonas fluorescens*. Mupirocin inhibits isoleucyl transfer-RNA synthetase, thereby arresting bacterial protein synthesis. Mupirocin has bacteriostatic properties at minimum inhibitory concentrations and bactericidal properties at the higher concentrations reached when applied locally.

Mechanism of Resistance

Low-level resistance in staphylococci is thought to result from point mutations within the usual staphylococcal chromosomal gene (ileS) for the target isoleucyl tRNA synthetase enzyme. High-level resistance in staphylococci has been shown to be due to a distinct, plasmid encoded isoleucyl tRNA synthetase enzyme. Intrinsic resistance in Gram negative organisms such as the *Enterobacteriaceae* could be due to poor penetration of the outer membrane of the Gram-negative bacterial cell wall. Due to its particular mode of action, and its unique chemical structure, mupirocin does not show any cross resistance with other clinically available antibiotics.

Microbiological Susceptibility

The prevalence of acquired resistance may vary geographically and with time for selected species, and local information on resistance is desirable, particularly when treating severe infections. As necessary, expert advice should be sought when the local prevalence of resistance is such that the utility of the agent in at least some types of infection is questionable.

Commonly susceptible species: *Staphylococcus aureus**, *Streptococcus pyogenes**, *Streptococcus* spp. (β-haemolytic, other than *S. pyogenes*).

Species for which acquired resistance may be a problem: *Staphylococcus* spp., coagulase negative.

Inherently resistant organisms: *Corynebacterium* spp. *Micrococcus* spp.

* Activity has been satisfactorily demonstrated in clinical studies.

5.2 Pharmacokinetic Properties

After topical application of mupirocin ointment, mupirocin is only very minimally absorbed systemically and that which is absorbed is rapidly metabolised to the anti-microbially inactive metabolite, monic acid. Penetration of mupirocin into the deeper epidermal and dermal layers of the skin is enhanced in traumatised skin and under occlusive dressings.

Elderly patients

No restrictions unless there is evidence of moderate or severe renal impairment.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Polyethylene Glycol 400

Polyethylene Glycol 3350

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf Life

24 months

6.4 Special Precautions for Storage

Store in a dry place below 30°C. Do not freeze. Protect from light and moisture. Keep out of reach of children.

6.5 Nature and Contents of Container

Aluminium tube with white HDPE screwcap 15 g

6.6 Special Precautions for Disposal and Other Handling

No special requirements. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Wash your hands after application.

7. PRODUCT REGISTRATION HOLDER

Synercam (M) Sdn. Bhd.,

A-17-7, Block A, Jaya One,

No. 72A, Jalan Profesor Diraja Ungku Aziz,

Seksyen 13, 46200 Petaling Jaya, Selangor

8. PRODUCT OWNER/ MANUFACTURER

Mepro Pharmaceuticals Private Limited

Unit II, Q Road, Phase IV Gidc,

Wadhwan City, Surendra Nagar, 363 035, India

9. PRODUCT REGISTRATION NUMBER

MALXXXXXXXAZ

10. LEAFLET REVISION DATE

18th August 2025

170.00 mm