BACTROBAN DERMAL

1. NAME OF THE MEDICINAL PRODUCT

Bactroban Dermal

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of ointment contains 20 mg mupirocin (2% w/w mupirocin free acid) .

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Ointment for topical administration.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Bactroban is a topical antibacterial agent, active against those organisms responsible for the majority of skin infections. Bactroban Dermal is used for skin infections, e.g. impetigo, folliculitis, furunculosis.

4.2 Posology and method of administration

Posology
Adults (including elderly/hepatically impaired) and children
Two to three times a day for up to ten days, depending on the response.

Renally impaired
See section 4.4

Method of administration
For topical administration.

A small quantity of Bactroban Dermal should be applied to cover the affected area. The treated area may be covered by a dressing.

Any product remaining at the end of treatment should be discarded.

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

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

This Bactroban dermal 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 Bactroban Dermal, 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.

Bactroban dermal is not suitable for:
- ophthalmic use
- intranasal use
- use in conjunction with cannulae and
- 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

No drug interactions have been identified.

4.6 Fertility, pregnancy and lactation

Pregnancy

Reproduction studies on Bactroban in animals have revealed no evidence of harm to the foetus (see section 5.3). As there is no clinical experience on its use during pregnancy, Bactroban should only be used in pregnancy when the potential benefits outweigh the possible risks of treatment.

Breast-feeding

There is no information on the excretion of Bactroban 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 (see section 5.3).

4.7 Effects on ability to drive and use machines

No adverse effects on the ability to drive or operate machinery have been identified.

4.8 Undesirable effects

Adverse reactions are listed below by system organ class and frequency. Frequencies are defined as: very common (≥1/10), common (≥1/100, <1/10), uncommon (≥1/1000, <1/100), rare (≥1/10,000, <1/1000), very rare (<1/10,000), including isolated reports.

Common and uncommon adverse reactions were determined from pooled safety data from a clinical trial population of 1573 treated patients encompassing 12 clinical studies. Very rare adverse reactions were primarily determined from post-marketing experience data and therefore refer to reporting rate rather than true frequency.

Immune system disorders:

Very rare: Systemic allergic reactions including anaphylaxis, generalised rash, urticaria and angioedema have been reported with Bactroban Dermal.

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.

Reporting of suspected adverse reactions

Reporting of suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form:

https://sideeffects.health.gov.il

Additionally, you should also report to GSK Israel (il.safety@gsk.com).

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.

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 Bactroban Dermal, mupirocin is only very minimally absorbed systemically and that which is absorbed is rapidly metabolised to the antimicrobially 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 (see section 4.4).

5.3 Preclinical safety data

Pre-clinical effects were seen only at exposures which are extremely unlikely to cause concern for humans under normal conditions of use. Mutagenicity studies revealed no risks to man.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polyethylene glycol 400
Polyethylene glycol 3350

6.2 Incompatibilities

None stated.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.
Use within 10 days after opening.

6.4 Special precautions for storage

Store below 25°C

6.5 Nature and contents of container

Sealed tamper evident lacquered aluminium tube containing 15 g ointment.

6.6 Special precautions for disposal and other handling

Any product remaining at the end of treatment should be discarded.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Wash your hands after application.

7. Manufacturer

Glaxo Operations (UK) Ltd., Barnard Castle, UK.

8. License Holder and Importer

GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva

9. License Number

037-75-25332

Revised in September 2022 according to MOHs guidelines

BacDer DR v5