

Bactroban™ Ointment

Mupirocin

QUALITATIVE AND QUANTITATIVE COMPOSITION

2% w/w Mupirocin free acid in a white, translucent, water soluble, polyethylene glycol base. For topical administration.

PHARMACEUTICAL FORM

Ointment.

CLINICAL PARTICULARS

Indications

Bactroban is a topical antibacterial agent, active against those organisms responsible for the majority of skin infections, e.g. Staphylococcus aureus, including methicillin-resistant strains, other staphylococci, streptococci. It is also active against Gram-negative organisms such as Escherichia coli and Haemophilus influenzae. Bactroban Ointment is used for skin infections, e.g. impetigo, folliculitis and furunculosis.

Dosage and Administration

Adults (including elderly) and Children:

Bactroban should be applied to the affected area up to three times daily, for up to 10 days. The area may be covered with a dressing or occluded if desired.

Topical. 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.

Contraindications

Hypersensitivity to Bactroban or other ointments containing polyethylene glycol and any of its constituents.

Warnings and Precautions

This Bactroban formulation is not suitable for ophthalmic use, intranasal use (in neonates or infants), use in conjunction with cannulae or at the site of central venous cannulation. When Bactroban is used on the face care should be taken to avoid the eyes. 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, Bactroban should be used with caution if there is evidence of moderate or severe renal impairment.

Interactions

None reported.

Pregnancy and Lactation

Adequate human data on use during pregnancy are not available. However, studies in experimental animals have shown Mupirocin to be without teratogenic effects.

Adequate human and animal data on use during lactation are not available.

Effects on Ability to Drive and Use Machines

No adverse effects on the ability to drive and use machines have been observed.

Adverse Reactions

Adverse reactions are listed below by system organ class and frequency. Frequencies are defined as: very common (greater than or equal to 1/10), common (greater than or equal to 1/100, less than 1/10), uncommon (greater than or equal to 1/1000, less than 1/100), rare (greater than or equal to 1/10,000, less than 1/1000), very rare (less than 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 have been reported with Bactroban 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.

Overdose

Not applicable.

PHARMACEUTICAL PARTICULARS

List of Excipients

Polyethylene glycol 400 USNF

Polyethylene Glycol 3350 USNF

Incompatibilities

None reported.

Special Precautions for Storage

Do not store above 25°C.

Instructions for Use/Handling

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

BACTROBAN is a trademark of the GlaxoSmithKline group of companies

Manufactured by:

Glaxo Operations UK Limited*

Barnard Castle

UK

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THIS IS A MEDICAMENT

Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.

Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.

- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- **Keep all medicaments out of the reach of children.**

Council of Arab Health Ministers,

Union of Arab Pharmacists.