BACTROBAN® NASAL

SCHEDULING STATUS:

S2

PROPRIETARY NAME AND DOSAGE FORM:

BACTROBAN® NASAL Ointment

COMPOSITION:

BACTROBAN NASAL ointment is a preparation of 2 g mupirocin as mupirocin calcium in 100 grams of base.

Excipients: Softisan 649 and White soft paraffin.

PHARMACOLOGICAL CLASSIFICATION:

A 20.1.6 Topical antibiotics

PHARMACOLOGICAL ACTION:

Pharmacodynamic properties:

Mupirocin is an antibiotic produced through fermentation of *Pseudomonas fluorescens* and inhibits bacterial protein synthesis by binding to bacterial isoleucyl t-RNA synthetase.

Pharmacokinetic properties:

Mupirocin is suitable only for topical application. Following intravenous or oral administration, mupirocin is metabolised to inactive monic acid.

INDICATIONS:

BACTROBAN NASAL ointment is indicated for the intranasal treatment of colonisation of the nasal passages by Staphylococcus strains including methicillin-resistant *Staphylococcus aureus* strains.

CONTRA-INDICATIONS:

BACTROBAN NASAL should not be given to patients with a history of hypersensitivity to any of its constituents.

BACTROBAN NASAL formulation is not suitable for ophthalmic use.

WARNINGS AND SPECIAL PRECAUTIONS:

In cases of sensitisation reaction or severe local irritation occurring with the use of BACTROBAN NASAL, treatment should be discontinued, the product should be wiped off and appropriate alternative therapy for the infection instituted.

Prolonged and intermittent use may result in overgrowth of non-susceptible *S. aureus* organisms.

PREGNANCY AND LACTATION:

The safety during pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE:

Apply a small quantity of BACTROBAN NASAL, about the size of a match head (approximately 30 mg of ointment) to each nostril twice a day for at least 5 days.

Dosage should not exceed 10 days.

Method of Administration:

Use a cotton tipped applicator.

After application, the nostrils should be closed by pressing the sides of the nose together several times.

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 in the antibacterial activity and potential loss of stability of the mupirocin in the ointment.

SIDE EFFECTS:

Side effects are listed below by system organ class and frequency. Frequencies are defined as: very common (≥1/10), common (≥1/100, <1/10), uncommon (≥1/1 000, <1/100), rare (≥1/10 000, <1/1 000), very rare (<1/10 000), including isolated reports. Uncommon adverse reactions were determined from pooled safety data from a clinical trial population of 422 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: Cutaneous hypersensitivity reactions.

Respiratory, thoracic and mediastinal disorders:

Uncommon: Nasal mucosa reactions.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

See Side Effects.

IDENTIFICATION:

BACTROBAN NASAL ointment is a white ointment packed in tubes.

PRESENTATION:

BACTROBAN NASAL ointment is available in 3 g tubes packed in an outer carton.

STORAGE INSTRUCTIONS:

Store below 25 °C.

It is recommended that any ointment remaining at the end of treatment is discarded.

Keep out of reach of children.

REGISTRATION NUMBER:

W/20.1.6/218

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

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