SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Bactroban 2% Nasal Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

3 PHARMACEUTICAL FORM

White soft paraffin based nasal ointment containing a glycerin ester.
Off-white smooth ointment.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

The elimination of nasal carriage of staphylococci, including methicillin resistant *Staphylococcus aureus* (MRSA)

4.2 Posology and method of administration

Posology
Adults (including the elderly) and children:
Bactroban Nasal Ointment should be applied to the anterior nares two to three times a day as follows:

A small amount of the ointment about the size of a match head is placed on the little finger and applied to the inside of each nostril. The nostrils are closed by pressing the sides of the nose together; this will spread the ointment throughout the nares. A cotton bud may be used instead of the little finger for the application in particular to infants or patients who are very ill.

Nasal carriage should normally clear within 5-7 days of commencing treatment.

Method of administration
Topical.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

Should a possible sensitisation reaction or severe local irritation occur with the use of Bactroban Nasal Ointment, treatment should be discontinued, the product should be wiped away 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.

This mupirocin nasal ointment formulation is not suitable for ophthalmic use.

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.

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.

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. Systemic allergic reactions including anaphylaxis, generalised rash, urticaria and angioedema.

Respiratory, thoracic and mediastinal disorders
Uncommon: Nasal mucosa reactions.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

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 spp.
Species for which acquired resistance may be a problem:
Methicillin-Resistant-*Staphylococcus aureus* (MRSA)
Methicillin-resistant coagulase-negative *Staphylococci* (MRCoNS)
Inherently resistant organisms:
Corynebacterium spp.
Micrococcus spp.

*Clinical efficacy has been demonstrated for susceptible isolates in approved clinical indications.

Mupirocin susceptibility (MIC) breakpoints for *Staphylococcus aureus*:

Susceptible: less than or equal to 1 mg/L
Resistant: greater than 256 mg/L

5.2 Pharmacokinetic properties

Studies have shown that following topical application of mupirocin there is very little systemic absorption of drug-related material. To mimic possible enhanced systemic penetration of mupirocin by application to damaged skin or a vascular site such as the mucous membrane, intravenous studies have been performed. Mupirocin was rapidly eliminated from the plasma by metabolism to monic acid, which in turn was excreted mainly in the urine.

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 clinical use. Mutagenicity studies revealed no risks to man.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

White soft paraffin
Softisan 649

6.2 Incompatibilities

None known

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store at room temperature (below 25°C)

6.5 Nature and contents of container

Lacquered aluminium tube fitted with a nozzle and screw cap containing 3 g ointment.

6.6 Special precautions for disposal

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 MARKETING AUTHORISATION HOLDER

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Brentford,
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Trading as:
GlaxoSmithKine UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 00038/0347

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 21 May 2008

10 DATE OF REVISION OF THE TEXT

16/12/2019