SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Bactroban 2% cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of cream contains: 21.5 mg Mupirocin calcium equivalent to 20.0 mg mupirocin.

Excipients with known effect
Each gram of cream contains 35 mg stearyl alcohol and 35 mg cetyl alcohol
Each gram of cream contains 10 mg benzyl alcohol

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cream.

Bactroban Cream is presented as a white cream of homogeneous appearance.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Bactroban Cream is indicated for the topical treatment of secondarily infected traumatic lesions such as small lacerations, sutured wounds or abrasions (up to 10 cm in length or 100 cm^2 in area), due to susceptible strains of *Staphylococcus aureus* and *Streptococcus pyogenes*.

4.2 Posology and method of administration

Posology

Adults/children ≥ 1 year/elderly
3 times a day for up to 10 days, depending on the response.
Patients not showing a clinical response within 3 to 5 days should be re-evaluated.
The duration of treatment should not exceed 10 days.

Children < 1 year
The safety and efficacy of Bactroban Cream in children aged less than one year have not yet been established. No data are available.

Hepatic impairment
No dosage adjustment is necessary.

Renal impairment
No dosage adjustment is necessary.

Method of administration

A thin layer of cream should be applied to the affected area with a piece of clean cotton wool or gauze swab.

The treated area may be covered by a dressing.

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 cream.

4.3 Contraindications

Hypersensitivity to mupirocin 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 Cream, 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.

Bactroban Cream formulation is not suitable for ophthalmic use and intranasal use.

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

Bactroban Cream contains cetyl alcohol and stearyl alcohol. These inactive ingredients may cause local skin reactions (e.g. contact dermatitis).
Bactroban Cream also contains 153 mg benzyl alcohol in each 15 g tube. This inactive ingredient may cause mild local irritation.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Pregnancy
Animal studies do not indicate reproductive toxicity (see section 5.3).
As there is no clinical experience on its use during pregnancy, mupirocin should only be used in pregnancy when the potential benefits outweigh the possible risks of treatment.

Breast-feeding
It is unknown whether mupirocin /metabolites are excreted in human 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

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

4.8 Undesirable effects

Data from clinical trials was used to determine the frequency of very common to rare undesirable effects. Very rare adverse reactions were primarily determined from post-marketing experience data and therefore refer to reporting rate rather than true frequency.

The following convention has been used for the classification of frequency:-
very common ≥1/10, common ≥1/100 and <1/10, uncommon ≥1/1000 and <1/100, rare ≥1/10,000 and <1/1000 , very rare <1/10,000.

Immune system disorders:
Very rare: Systemic allergic reactions including anaphylaxis, generalised rash, urticaria and angioedema

Skin and subcutaneous tissue disorders:
Common: Application site hypersensitivity reactions including urticaria, pruritus, erythema, burning sensation, contact dermatitis, rash

Skin dryness and erythema have been reported in irritancy studies in volunteers.

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
There is currently limited experience with overdosage of Bactroban Cream.

Management
There is no specific treatment for an overdose of Bactroban Cream. 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: Dermatologicals ATC code: D06AX09, Antibiotics and chemotherapeutics for dermatological use

Mechanism 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

Absorption

Systemic absorption of mupirocin through intact human skin is low although it may occur through broken/diseased skin. However, clinical trials have shown that when

given systemically, it is metabolised to the microbiologically inactive metabolite monic acid and rapidly excreted.

Elimination
Mupirocin is rapidly eliminated from the body by metabolism to its inactive metabolite monic acid which is rapidly excreted by the kidney.

5.3 Preclinical safety data

Effects in non-clinical studies were observed only at exposures considered sufficiently in excess of the maximum human exposure indicating little relevance to clinical use. Mutagenicity studies revealed no risks to man.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Xanthan gum
Liquid paraffin
Cetomacrogol 1000
Stearyl alcohol
Cetyl alcohol
Phenoxyethanol
Benzyl alcohol
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

18 months

6.4 Special precautions for storage

Do not store above 25°C. Do not freeze.

6.5 Nature and contents of container

Squeezable aluminium tubes with a screw cap containing 15 g of white cream.

6.6 Special precautions for disposal

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

7. MARKETING AUTHORISATION HOLDER

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London
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Trading as:
GlaxoSmithKline UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 00038/0372

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

21/02/2020

10 DATE OF REVISION OF THE TEXT

11/12/2024