BACTROBAN® TOPICAL

SCHEDULING STATUS:

S2

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

BACTROBAN® TOPICAL Ointment

Mupirocin 2 % (*m/m*)

Read all of this leaflet carefully because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Do not share BACTROBAN TOPICAL with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

WHAT BACTROBAN TOPICAL CONTAINS:

Each gram of BACTROBAN TOPICAL contains 20 mg of mupirocin.

The other ingredient is polyethylene glycol.

WHAT BACTROBAN TOPICAL IS USED FOR:

BACTROBAN TOPICAL is an antibiotic. It is used to treat skin infections caused by bacteria.

BEFORE YOU USE BACTROBAN TOPICAL:

Do not use BACTROBAN TOPICAL

- If you have previously had an allergic reaction to BACTROBAN TOPICAL, or any of its ingredients. The active substance and other ingredients in BACTROBAN TOPICAL are listed at the beginning of this leaflet.

Take special care with BACTROBAN TOPICAL:

BACTROBAN TOPICAL can cause skin irritation and allergic reactions (see Possible Side Effects).

BACTROBAN TOPICAL is not suitable for:

- eye infections
- use inside your nose - there is a different preparation of BACTROBAN NASAL for this
- skin near tubes inserted into your body for the delivery or removal of fluid (cannulae).

Keep the ointment away from your eyes. If the ointment gets into your eyes accidentally, rinse your eyes thoroughly with water.

BACTROBAN TOPICAL contains polyethylene glycol, which in large quantities can cause kidney damage. Avoid applying BACTROBAN TOPICAL to large areas of broken or damaged skin, especially if you have problems with your kidneys.

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care professional for advice before using BACTROBAN. Safety in pregnancy and breastfeeding has not been established.

Taking other medicines with BACTROBAN TOPICAL:

Always tell your health care professional if you are taking any other medicine. (This includes complementary or traditional medicines).

HOW TO USE BACTROBAN TOPICAL:

Do not share medicines prescribed for you with any other person.

Always use BACTROBAN TOPICAL exactly as your doctor has told you to. Check with your doctor or pharmacist if you are not sure.

- Wash your hands before and after applying BACTROBAN TOPICAL.
- With a piece of clean cotton wool or a gauze swab, apply a small quantity of BACTROBAN TOPICAL to cover the affected area.
- After applying the ointment, you may cover the treated area with a sterile bandage or gauze dressing, unless your doctor has told you to leave it uncovered.
- Use BACTROBAN TOPICAL two or three times a day for up to ten days.
- Do not mix BACTROBAN TOPICAL with other lotions, creams or ointments. This may dilute BACTROBAN TOPICAL, which may affect your treatment.

It is important that you take the full course of BACTROBAN TOPICAL. Do not stop treatment early as your symptoms may disappear before the infection is fully cleared.

If you forget to use BACTROBAN TOPICAL:

Apply BACTROBAN TOPICAL as soon as you remember, and apply the next dose at the usual time.

If you use too much BACTROBAN TOPICAL:

Carefully wipe off the extra ointment. Problems of overdosage with this medicine are unlikely.

If you accidentally swallow BACTROBAN TOPICAL contact your doctor or pharmacist for advice.

POSSIBLE SIDE EFFECTS:

BACTROBAN TOPICAL can have side effects.

BACTROBAN TOPICAL can cause severe allergic reactions. Signs include:

- raised and itchy rash
- swelling, sometimes of the face or mouth, causing difficulty in breathing
- collapse.

Contact a doctor immediately if you get any of the above symptoms, and stop using BACTROBAN TOPICAL.

BACTROBAN TOPICAL can cause skin irritation.

- If you get skin irritation, stop using BACTROBAN TOPICAL. Wipe off any ointment and tell your doctor as soon as possible.

Frequent side effects:

- burning at the place where the ointment is applied.

Less frequent:

- itching, redness, stinging and/or dryness on your skin in the place where the ointment is applied
- allergic reactions.

If any of these side effects get serious, please tell your doctor or pharmacist.

Not all side effects reported for BACTROBAN TOPICAL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using this medicine, please consult your doctor, pharmacist or other health care professional for advice.

STORING AND DISPOSING OF BACTROBAN TOPICAL:

Store all medicines out of reach of children.

Store below 25 °C.

Do not use after the expiry date shown on the pack.

Dispose of any BACTROBAN TOPICAL remaining at the end of treatment.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

PRESENTATION OF BACTROBAN TOPICAL:

BACTROBAN TOPICAL is available in 15 g and 100 g tubes each packed in an outer carton.

IDENTIFICATION OF BACTROBAN TOPICAL:

BACTROBAN TOPICAL is an off-white coloured ointment.

REGISTRATION NUMBER:

T/20.1.6/75

NAME AND ADDRESS OF REGISTRATION HOLDER:

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

DATE OF PUBLICATION:

Last approval: 6 December 2013

Date compliant with Regulation 10: 03 March 2016

1.3.2 Patient Information Leaflet

Update History:

15-02-2000: As per MDS-005. MCC approved 20/04/2000

27-08-2002: Company name change of the Applicant

14-03-2003: New address of the Applicant reflected.

Proposed Package Insert 19 January 2011 In-Line With GDS 011-013

Response to CCC recommendation dated 3 July 2013. Submitted 23 September 2013

Approved 6 December 2013

GDS13 submitted 20 May 2014

Implementation of Regulation 9 and 10: 03 March 2016