BACTROBAN OINTMENT (PHILIPPINES)

Mupirocin (2% w/w)

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What Bactroban is used for

Bactroban is a topical antibacterial ointment used to prevent or treat bacterial skin infections such as an infectious skin infection with blistering and crusting known as "impetigo", infected hair follicles which form pimples containing pus known as "folliculitis" and recurring boils known as "furunculosis".

How Bactroban works

Bactroban is an antibiotic produced through fermentation by Pseudomonas fluorescens. When absorbed into the skin, it prevents formation of bacterial protein and kills the bacteria when applied to infected skin area.

Before you use Bactroban

- When you must not use it Do not use Bactroban
- if you are allergic (hypersensitive) to mupirocin or any other ingredients of Bactroban.

If you think this may apply to you, do not use Bactroban until you have checked with your doctor.

- Before you start to use it

Bactroban can cause skin irritation and allergic reactions.

Bactroban ointment is not suitable for:

- eve infections
- use inside your nose
- 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, wash them thoroughly with water.

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

There is only limited information about the safety of Bactroban in pregnant women. If you are pregnant, or think you could be, or if you are planning to become pregnant, do not take Bactroban without checking with your doctor.

It is not known whether the ingredients of Bactroban can pass into breast milk. If you are breast-feeding, you must check with your doctor before you take Bactroban.

If you are using Bactroban on a cracked nipple, wash the nipple well before breast feeding your baby.

Taking other medicines

Tell your doctor or pharmacist if you're taking any other medicines, if you've taken any recently, or if you start taking new ones. This includes medicines you bought without a prescription.

How to use Bactroban

- <u>How much to use</u>

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

How to use

- Wash your hands before and after applying Bactroban.
- With a piece of clean cotton wool or a gauze swab, apply a small quantity of Bactroban ointment 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.
- Do not mix Bactroban with other lotions, creams or ointments. This may dilute Bactroban, which may affect your treatment.

- When to use it

You should use Bactroban two or three times a day for up to ten days, depending on the response.

- How long to use it

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

- If you forget to use it Apply Bactroban as soon as you remember, and apply the next dose at the usual time.

- <u>If you use too much</u> (overdose)

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

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

While you are using it

- <u>Things you must do</u>
 Check with your doctor or
 pharmacist before taking your
 medicine and take it as
 prescribed by your doctor.
- Things you must not do
 This medicine has been
 prescribed for you. Do not pass
 it on to others. It may harm
 them, even if their symptoms are
 the same as yours.
- Things to be careful of
 If you develop an allergic
 reaction (such as a rash, local
 pain or swelling) while using
 Bactroban ointment, stop using
 the preparation and tell the
 doctor at once.

Side Effects

Like all medicines, Bactroban can cause side effects, but not everybody gets them.

Conditions you need to look out for

Severe allergic reactions
These are very rare in people taking Bactroban. Signs include:

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

Contact a doctor immediately if you get any of these symptoms. Stop using Bactroban.

Bactroban can cause skin irritation

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

Common side effects

These may affect up to 1 in 10 people:

• burning at the place where the ointment is applied.

<u>Uncommon side effects</u> These may affect up to 1 in 100

These may affect up to 1 in 100 people:

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

Very rare side effects These may affect up to 1 in 10,000 people:

• Allergic reactions

Tell your doctor or pharmacist if any of the side effects listed becomes severe or troublesome, or if you notice any side effects not listed in this leaflet.

You may report any side effects of adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835549, or visiting the website npra.moh.gov.my (Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines).

Storage and Disposal of Bactroban

Storage
Keep out of reach and sight of children.
 Do not store Bactroban above 25 °C (77 °F).

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

Dispose of any Bactroban remaining at the end of the treatment.

- Disposal

Do not dispose of the medicine in waste water or household rubbish. Ask your pharmacist how to dispose of medicines no longer required. This will help to protect the environment.

Product Description

- What it looks like
Bactroban is a white,
translucent, water soluble, and
polyethylene glycol base
ointment.

- Ingredients

- Active ingredient(s) Each gram of Bactroban contains 20 mg mupirocin
- Inactive ingredient(s) Polyethylene glycol
- <u>MAL number</u> MAL19992362ARZ

Manufacturer

SmithKline Beecham Don Celso Tuason Avenue, Cainta, Rizal, Philippines

Product Registration Holder

GlaxoSmithKline Pharmaceutical Sdn. Bhd. Level 6, Quill 9, 112 Jalan Semangat, 46300 Petaling Jaya, Selangor, Malaysia

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