

PACKAGE LEAFLET: INFORMATION FOR THE USER

BACTROBAN® 2% OINTMENT
MUPIROICIN 2% OINTMENT
(mupirocin)

Your medicine is known by either of the above names but will be referred to as Bactroban throughout the following leaflet.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1 What Bactroban is and what it is used for

Bactroban 2% Ointment (called 'Bactroban' in this leaflet) contains the active substance called mupirocin. Bactroban is an antibiotic ointment.

It is used:

- to treat skin infections on the skin such as
 - infected hair follicles which form pimples containing pus ("folliculitis"),
 - an infectious skin infection with blistering and crusting known as "impetigo" or
 - recurring boils ("furunculosis")
- to kill various bacteria which cause other skin infections including *Staphylococci*, *Streptococci* and *E. coli*. This group includes MRSA (Methicillin Resistant *Staphylococcus aureus*).
- This ointment is for external use on your skin only.

2 What you need to know before you use Bactroban

Do not use Bactroban:

- if you are allergic (hypersensitive) to mupirocin or any of the other ingredients of this medicine (listed in section 6).

Do not use if the above applies to you. If you are not sure do not use this medicine. Talk to your doctor, nurse or pharmacist before using Bactroban.

Warnings and precautions

- Bactroban can cause severe skin reactions or allergies. See 'Conditions to look out for' in Section 4
- Bactroban is not suitable for use in your eyes, nose or around intravenous cannula ('drip') sites.

Thrush (a yeast infection) may develop if Bactroban is used for a long time. If this occurs, tell your doctor, pharmacist or nurse.

Keep the ointment away from your eyes.

- If the ointment gets into your eyes accidentally, wash them thoroughly with water.

Other medicines and Bactroban

Tell your doctor, nurse or pharmacist if you are using, have recently used or might use any other medicines.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

If a cracked nipple is being treated, the ointment must be thoroughly washed off prior to breast-feeding.

Driving and using machines

It is unlikely that Bactroban will affect your ability to drive or operate machinery.

Bactroban Ointment contains polyethylene glycol

Talk to your doctor before using this medicine if you:

- have kidney problems
- have large areas of open wounds or damaged skin to be treated

3 How to use Bactroban

Always use this medicine exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

Using this medicine

Do not mix Bactroban with any other external cream or ointment medicines on the infected area of your skin as this may reduce the effectiveness of Bactroban.

You usually apply Bactroban on your skin two to three times a day.

1. Wash and dry your hands.
2. Apply ointment to the infected area of your skin.
3. You can cover the treated area with a plaster(s) or suitable dressing(s), unless your doctor has told you to leave it uncovered.
4. Replace the cap on the tube and wash your hands.

How long should you use Bactroban for?

Use Bactroban for as long as your doctor has told you. If you are not sure, ask your doctor, nurse or pharmacist. The bacteria are normally cleared from your skin within 10 days of starting treatment. Do not use for more than 10 days. Throw away any ointment that is left over.

If you swallow any Bactroban

If you swallow any of the ointment, speak to your doctor, nurse or pharmacist for advice.

If you forget to use Bactroban

- If you forget to apply Bactroban, apply it as soon as you remember.
- If your next dose is due within an hour, skip the missed dose.
- Do not use a double dose to make up for a forgotten dose.

If you stop using Bactroban

If you stop using Bactroban too early, not all the bacteria may have been killed or they may continue to grow. Ask your doctor, nurse or pharmacist when to stop using the ointment. If you have any further questions on the use of this product, ask your doctor, nurse or pharmacist.

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Conditions to look out for

Severe skin reactions or allergies:

These are very rare in people using Bactroban Ointment. 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
- If you develop a severe skin reaction or an allergy:
 - wash off the ointment
 - stop using it and
 - tell your doctor as soon as possible.

On rare occasions, medicines like Bactroban can cause inflammation of the colon (large intestine), causing diarrhoea, usually with blood and mucus, stomach pain, fever (*pseudomembranous colitis*).

- **Tell your doctor as soon as possible** if you get any of these symptoms.

The following side effects may happen with this medicine:

Common (may affect up to 1 in 10 people)

- Burning where the ointment is applied.

Uncommon (may affect up to 1 in 100 people)

- Itching, redness, stinging and dryness on your skin in the place where Bactroban is applied.
- Allergic rash, itching, redness or soreness of the skin can also occur on other parts of your body.

Very rare (may affect up to 1 in 10,000 people)

- Swollen face and/or difficulty breathing. This may be a sign of a serious allergic reaction that could require emergency treatment.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.

5 How to store Bactroban

- **KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.**
- Bactroban should be stored at room temperature, below 25°C.
- Do not use after the expiry date printed on the carton or tube label. The expiry date refers to the last day of that month.
- Once opened, the shelf life of this medicine is 10 days.
- If your doctor tells you to stop using the ointment, please take it back to the pharmacist for safe disposal. Only keep the ointment if your doctor tells you to.
- If the ointment becomes discoloured or shows any other signs of deterioration, you should seek the advice of your pharmacist before using it.
- 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.

6 Contents of the pack and other information

What Bactroban contains

- The active substance is mupirocin. Each gram of ointment contains 20 mg mupirocin.
- The other ingredients are polyethylene glycol 400 and polyethylene glycol 3350.

What Bactroban looks like and contents of the pack

Bactroban is a white, clear ointment.

Bactroban is available as 15g tubes of ointment.

Product Licence holder

Procured from within the EU and repackaged by the Product Licence holder: Chemilines Ltd., Chemilines House, Alperton Lane, Wembley, Middlesex HA0 1DX.

Manufacturer

GlaxoSmithKline Pharmaceuticals S.A., ul. Grunwaldzka 189, 60-322 Poznan, Poland.

Or

GlaxoSmithKline Trading Services Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland.

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