

PACKAGE LEAFLET: INFORMATION FOR THE USER

BACTROBAN® 2% NASAL OINTMENT**MUIPIROCIN 2% NASAL OINTMENT**
(mupirocin calcium)

Your medicine is known as 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

- 1 What Bactroban is and what it is used for
- 2 What you need to know before you use Bactroban
- 3 How to use Bactroban
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1 WHAT BACTROBAN IS AND WHAT IT IS USED FOR

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

It is used:

- to kill a group of bacteria in the nose called 'Staphylococci'
- this group includes MRSA (Methicillin Resistant *Staphylococcus aureus*)
- this ointment is for use in your nose only.

2 WHAT YOU NEED TO KNOW BEFORE YOU USE BACTROBAN**Do not use Bactroban:**

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

If you are not sure if this applies to you, 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

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To update the manufacturers from

Glaxo Wellcome Operations, Harmine Road, Barnard Castle, DL12 8DT, UK

To

Glaxo Wellcome Operations, Harmine Road, Barnard Castle, DL12 8DT, UK

Or

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

With consequential changes to the labels and leaflet.

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

Using this medicine

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

- 1 Wash and dry your hands.
- 2 Place a small amount of Bactroban, about the size of a match head, on your little finger.
- 3 Apply this to the inside of one nostril.
- 4 Repeat steps 2 and 3 for your other nostril.
- 5 Press the sides of your nose together to spread the ointment around the nostril.
- 6 Replace the cap on the tube and wash your hands.

A cotton bud can be used instead of your little finger to apply the ointment, particularly in infants or the very ill.

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 nose within 5 to 7 days of starting treatment.

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. 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:

Uncommon (may affect up to 1 in 100 people)

- Itching, redness, burning, tingling or stinging of the nose.

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

- Some people can develop a skin reaction or allergy that is severe. The signs can include a rash, itchiness, redness or soreness.

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

- Do not store above 25°C.
- **KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.**
- If your doctor tells you to stop using the medicine, please take it back to the pharmacist for safe disposal. Only keep the medicine if your doctor tells you to.
- Do not use Bactroban after the expiry date which is stated on the tube. The expiry date refers to the last day of that month.
- If the medicine becomes discoloured or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.
- 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

- Bactroban contains mupirocin calcium equivalent to 2%w/w of the active ingredient, mupirocin, in a white base.
- Bactroban also includes the following: white soft paraffin and Softisan 649.

What Bactroban Nasal Ointment looks like and contents of the pack

- Bactroban is a white ointment in an aluminium tube.
- Bactroban is available as a tube containing 3g of ointment.

Product Licence holder

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

Manufacturer

This product is manufactured by:

- Glaxo Wellcome Operations, Harmire Road, Barnard Castle, DL12 8DT, UK.

Or

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

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