

Reason for update: Type Iain Project Pine CMC update (Pzn address is grey shaded therefore no live artwork impacted thus no change to date in PIL)

Agency Approval Date: 30/06/2022 (imp date for Type IAIN)

Text Date: 10/06/2022

Text Issue and Draft No.: Issue 8 draft 1

Package leaflet: Information for the user

Bactroban 2% w/w Ointment mupirocin

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.
- In this leaflet, Bactroban 2% w/w Ointment will be called Bactroban.

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
4. Possible side effects
5. How to store Bactroban
6. Contents of the pack and other information

1 What Bactroban is and what it is used for

Bactroban contains the active substance 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"
 - recurring boils ("furunculosis")
- 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 to mupirocin or any of the ingredients of this medicine (listed in section 6).
- if you have kidney problems as the ointment contains polyethylene glycol.

Warnings and Precautions

- Talk to your doctor or pharmacist before using Bactroban. Do not use Bactroban in your nose or eyes. If you are using Bactroban on your face, be careful not to use it in or near your eyes or nose. For infections of the inner nose, a different ointment will be prescribed.
- Do not put Bactroban into your mouth or swallow it.
- If you are using Bactroban on your face, do not get it in your eyes. If you get it in your eyes, wash it out immediately.
- If you develop a severe skin reaction or allergy wash the ointment off, stop using it and tell your doctor as soon as possible.
- Prolonged use of Bactroban may result in overgrowth of non-susceptible organisms.

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Other medicines and Bactroban

Tell your doctor, pharmacist or nurse 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 baby, ask your doctor or pharmacist before taking this medicine. If a cracked nipple is to be treated, it should be thoroughly washed prior to breast-feeding.

Driving and using machines

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

3 How to use Bactroban

Always use Bactroban exactly as your doctor has told you. Check with your doctor, nurse 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 up 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.

Any product remaining at the end of treatment should be discarded.

If you use more Bactroban than you should

If you use more Bactroban than you should, 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.

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4 Possible side effects

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

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/or 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)

- Raised and itchy rash, swelling, sometimes of the face or mouth, causing difficulty in breathing, collapse or loss of consciousness. This may be a sign of a serious allergic reaction that could require emergency treatment.

If you develop a severe skin reaction or allergy:

- wipe 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.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Bactroban

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C.
- Do not use this medicine after the expiry date which is stated on the tube or carton after (EXP). The expiry date refers to the last day of that month.
- Bactroban is a white sterile ointment. Do not use if it looks different to normal.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

What Bactroban contains

- The active substance is mupirocin. Each 1 g of ointment contains 20 mg of mupirocin (2% w/w mupirocin free acid).
- The other ingredients are macrogol 400 and macrogol 3350.

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What Bactroban looks like and contents of the pack

- Bactroban is a white sterile ointment.
- Bactroban is available in a 15 g tube. Each tube comes in a carton.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

GlaxoSmithKline (Ireland) Limited
12 Riverwalk
Citywest Business Campus
Dublin 24

Manufacturer:

Delpharm Poznań Spółka Akcyjna
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60-322 Poznań
Poland

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

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