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Market: Ireland

Agency Approval Date: 30/06/2022

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Package leaflet: Information for the user

Bactroban 2.0% w/w Nasal 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 2.0% w/w Nasal 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 as 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 to mupirocin or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using Bactroban

- Do not put Bactroban into your mouth or swallow it.
- Do not put Bactroban in your eyes. If you get it in your eyes, wash it out immediately.
- If you develop a severe skin reaction or allergy wipe off the ointment, stop using it and tell your doctor as soon as possible.
- Prolonged use of Bactroban may result in overgrowth of non-susceptible organisms.

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 taking this medicine.

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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 this medicine exactly as your doctor has told you. Check with your doctor, nurse or pharmacist if you are not sure.

Using this medicine

You usually apply Bactroban to your nose two or 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.

Small children or very ill people

Use a cotton bud instead of your little finger to apply the ointment. With these patients, special care should be taken.

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. 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.

4 Possible side effects

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

The following side effects may happen with this medicine:

Uncommon (may affect up to 1 in 100 people)

- a runny nose
- itching, redness, burning, tingling and/or stinging of the nose.

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

- Allergic rash, itching, redness or soreness of the skin can also occur on other parts of your body.
- 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:

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- 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, Website: www.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 an off-white smooth ointment. Do not use it 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 nasal ointment contains 20 mg of mupirocin (as mupirocin calcium).
- The other ingredients are white soft paraffin and mixed diglycerin ester of fatty acids (Softisan 649).

What Bactroban looks like and contents of the pack

- Bactroban is an off-white smooth ointment.
- Bactroban is available in a 3 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

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Dublin 24

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