

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH
THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986**

The medicine is dispensed with a physician's prescription only

Bactroban Nasal ointment

Each gram contains 20 mg mupirocin (as calcium) (2% w/w)

The list of the additional ingredients is detailed in section 6.

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the physician or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

1. What is the medicine intended for?

Bactroban Nasal contains an active ingredient called mupirocin calcium.

It is used:

- To kill a group of bacteria in the nose called '*Staphylococci*'
- This group includes methicillin-resistant *Staphylococcus aureus* (MRSA)
- This ointment is intended for use in your nose only.

Therapeutic group

Antibiotic for topical use.

2. Before using the medicine

Do not use the medicine if:

- You are sensitive (allergic) to mupirocin calcium, mupirocin or any of the additional ingredients contained in the medicine (detailed in section 6).

If you are not sure if this applies to you, do not use this medicine. Refer to your physician or pharmacist before using Bactroban Nasal.

Special warnings regarding use of the medicine

Bactroban Nasal can cause allergies or severe skin reactions. See 'Conditions to look out for' in Section 4.

Do not use this medicine frequently, or for a prolonged period, without consulting a physician.

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

Keep the ointment away from your eyes.

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

If you are taking, or have recently taken, other medicines, including non-prescription medicines, herbal medicines and nutritional supplements, tell the physician or the pharmacist.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to become pregnant, refer to your physician or pharmacist for advice before using this medicine.

Driving and using machines

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

3. How should you use the medicine?

Always use the preparation according to the physician's instructions. Check with the physician or the pharmacist if you are uncertain about the preparation dosage and treatment regimen.

Using this medicine

The dosage and treatment regimen will be determined by the physician only.

The usual dosage is generally twice a day.

1. Wash and dry your hands.
2. Place a small amount of Bactroban Nasal, about the size of a match head, on your little finger.
3. Apply it 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 in 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 very ill patients.

Do not exceed the recommended dose

How long should you use Bactroban Nasal?

Use Bactroban Nasal for as long as your physician has instructed you to. If you are not sure, ask your physician or pharmacist. The bacteria are normally cleared from your nose within 3 to 5 days of starting treatment. Do not use for more than 10 days. Throw away any ointment that is left over.

If you swallowed Bactroban Nasal

If you swallowed the ointment, consult your physician or pharmacist.

If a child has accidentally swallowed the medicine, refer immediately to a physician or to a hospital emergency room and bring the package of the medicine with you.

If you forget to use Bactroban Nasal

- If you forgot to apply Bactroban Nasal, apply it as soon as you remember
- If your next dose is supposed to be applied within one hour, skip the missed dose
- Do not use a double dose to make up for a forgotten dose.

Adhere to the treatment regimen as recommended by the physician.

If you stop using Bactroban Nasal

If you stop using Bactroban Nasal too early, not all the bacteria may have been killed or they may continue to multiply. Ask your physician or pharmacist when to stop using the ointment.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the physician or pharmacist.

4. Side effects

As with any medicine, use of Bactroban Nasal may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not suffer from any of them.

Conditions to look out for

Allergies or severe skin reactions:

These are very rare in people using Bactroban Nasal. Signs include:

- Raised and itchy rash
 - Swelling, sometimes of the face or mouth, causing difficulty in breathing
 - Collapse or loss of consciousness.
- **Contact a physician immediately** if you get any of these symptoms. Stop using Bactroban Nasal.
- If you develop a severe skin reaction or an allergy:
 - Wash off the ointment
 - Stop using it
 - Tell your physician as soon as possible.

On rare occasions, medicines like Bactroban Nasal can cause inflammation of the colon, causing diarrhea, usually accompanied by blood and mucus, abdominal pain and fever (*pseudomembranous colitis*).

→ **Contact a physician as soon as possible** if you get any of these symptoms.

The following side effects may occur with this medicine:

Uncommon side effects (may occur in up to 1 in 100 people)

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

Very rare side effects (may occur in 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.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect that has not been mentioned in the leaflet, consult with the physician.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il), which directs you to the online form for reporting side effects, or by entering the link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>.

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the sight and reach of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the physician.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store below 25°C.
- Bactroban Nasal is an off-white ointment. Do not use it if it looks different than normal.

6. Additional information

- In addition to the active ingredient, the medicine also contains:
White soft paraffin and Softisan 649
- What the medicine looks like and the content of the package:
 - Bactroban Nasal is an off-white ointment.
 - Bactroban Nasal comes in a 3 gram tube. Each tube comes in a carton.
- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Manufacturer: Glaxo Operations (UK) Ltd., Barnard Castle, UK.
- This leaflet was checked and approved by the Ministry of Health in January 2015, and was updated in accordance with the Ministry of Health guidelines in February 2019.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 050-85-26431.

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