

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

The medicine is dispensed according to a physician's prescription only

Bactroban Dermal, ointment

Each 1 gram contains 20 mg mupirocin (2% w/w)

For the list of the inactive and allergenic ingredients in the medicine, see section 2 – “Important information about some of the ingredients in the medicine” and section 6 – “Additional information”.

Read this 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 Dermal contains the active ingredient called mupirocin.

It is used to treat skin infections 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.

Therapeutic group:

Antibiotic for topical use.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you are sensitive (allergic) to mupirocin or to any of the additional ingredients contained in 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. Contact your physician or pharmacist before using Bactroban Dermal.

- Do not use this medicine in your eyes, nose or around intravenous cannula ('drip') sites.

Special warnings regarding use of the medicine

- Bactroban Dermal may cause severe skin reactions or allergies. See in section 4 'Side Effects'.
- Do not use this medicine frequently, or for a prolonged period, without consulting a physician. Thrush (a yeast infection) may develop if Bactroban Dermal is used for a long time. If this occurs, tell the physician or pharmacist.

Avoid contact between the ointment and your eyes.

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

Drug interactions

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

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 physician 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 this medicine will affect your ability to drive or use machines.

Important information about some of the ingredients in the medicine

Bactroban Dermal contains polyethylene glycol; talk to your physician before using this medicine if you have:

- kidney problems
- large areas of open wounds or damaged skin that need to be treated.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the physician's instructions.

Check with the physician or pharmacist if you are uncertain about the preparation dosage and treatment regimen.

Using this medicine

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

The dosage and treatment regimen will be determined by the physician only. The recommended dosage is usually:

Application of Bactroban Dermal on the skin two to three times a day.

1. Wash and dry your hands.
2. Apply the 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 physician has told you to leave it uncovered.
4. Replace the cap on the tube and wash your hands.

Do not exceed the recommended dose

Duration of treatment

Use Bactroban Dermal for as long as your physician has told you. If you are uncertain, ask your physician or pharmacist. The bacteria are normally cleared from your skin within 10 days of starting treatment. Do not use Bactroban Dermal for more than 10 days. Discard any remaining ointment.

Do not swallow!

This medicine is intended for external use only.

If you have accidentally swallowed some ointment

If you have accidentally swallowed some ointment, consult your physician or pharmacist.

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

If you forgot to take the medicine

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

Adhere to the treatment regimen recommended by your physician. Even if your health condition improves, do not stop treatment with the medicine without consulting the physician.

If you stop taking the medicine

If you stop using Bactroban Dermal too early, not all the bacteria may have been killed or they may continue to grow. 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 Dermal 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.

Discontinue use and contact a physician immediately in the following cases:

Severe skin reactions or allergies - these effects are very rare in people using Bactroban Dermal. Signs include:

- Raised and itchy rash

- Swelling, sometimes of the face or mouth, causing difficulty in breathing
 - Collapse or loss of consciousness.
- If you experience any of these symptoms, **contact your physician immediately** and stop using Bactroban Dermal.

If you develop a severe skin reaction or allergy:

- wash off the ointment
- stop using the ointment
- contact your physician as soon as possible.

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

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

The following side effects may occur when using this medicine:

Common side effects

These may affect **up to 1 in 10** people:

- Burning sensation where the ointment is applied.

Uncommon side effects

These may affect **up to 1 in 100** people:

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

Very rare side effects

These 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.

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

Reporting side effects

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) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.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 reach and sight 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.
- Use the ointment within 10 days after first opening, but no later than the expiry date of the preparation.
- Store below 25°C.
- Bactroban Dermal is an off-white, semi-transparent ointment. Do not use it if it looks different than normal.
- Do not discard medicines in the wastewater or household waste bin. Ask the pharmacist how to dispose of medicines that are no longer in use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

- In addition to the active ingredient, the medicine also contains:
Polyethylene glycol 400, polyethylene glycol 3350
- What the medicine looks like and the contents of the package:
 - Bactroban Dermal is an off-white, semi-transparent ointment.
 - Bactroban Dermal comes in a tube containing 15 grams. Each tube is packaged in a carton.
- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Manufacturer: Glaxo Operations (UK) Ltd., Barnard Castle, UK.

- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 037-75-25332

Revised in September 2022 according to MoH guidelines.

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