

Patient package insert according to Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a physician's prescription only

Staphiderm Cream

Active ingredient and its concentration: fusidic acid 2%

Inactive ingredients and allergens: see section 2 under "Important information about some of this medicine's ingredients" and section 6 "Additional information".

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, consult your physician or pharmacist.

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

1. What is this medicine intended for?

Staphiderm Cream is an antibiotic preparation for local treatment of bacterial skin infections susceptible to the preparation.

Therapeutic group: topical antibiotic.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients in this medicine (see section 6).

Special warnings about using this medicine:

- Do not use Staphiderm Cream for a long time, as prolonged use may increase the risk of bacterial resistance to the antibiotic, thus reducing the effectiveness of the medicine.
- Avoid contact between the cream and the eyes (e.g., if accidentally passed from your hands or by using it too close to your eyes), which may cause eye irritation (burning).

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your physician or pharmacist.

Pregnancy and breastfeeding

If you are pregnant, think you may be pregnant, planning to have a baby or breastfeeding, ask your physician for

advice before using this medicine.

- Staphiderm Cream may be used if you are pregnant or think you might be pregnant.
- Staphiderm Cream may be used if you are breastfeeding, but do not apply the cream to the breast area.

Driving and using machines

This medicine usually has no effect on your ability to drive or operate machinery. Nevertheless, if you feel any side effect that may harm your ability to drive or operate machinery, consult your physician.

Important information about some of this medicine's ingredients

Staphiderm Cream contains:

Cetostearyl alcohol, which may cause local skin reactions (e.g. contact dermatitis).

Chlorocresol, which may cause allergic reactions.

3. How to use this medicine

Always use the medicine according to your physician's instructions. Check with your physician or pharmacist if you are not sure about your dose or about how to take this medicine. Only your physician will determine your dose and how you should take this medicine. The recommended dosage is usually:

Apply the cream on the affected area 3-4 times a day, but less often if the affected area is covered with a bandage. You should notice an improvement after a few days of using Staphiderm Cream. If there is no improvement after seven days, stop using the medicine and contact the physician.

Do not exceed the recommended dose.

Duration of treatment with the medicine is usually up to two weeks; consult your physician before using this medicine for a longer period of time. Prolonged use may cause resistance to the medicine.

If you forget to apply this medicine at the scheduled time, apply it as soon as you remember. Afterwards, carry on using it at the usual scheduled time.

Directions of use: Do not swallow! This medicine is intended for external use only.

Wash your hands before using Staphiderm Cream. Rub the cream on the skin. If your physician has told you to use Staphiderm Cream on your face, avoid contact with your eyes.

If the preparation accidentally came in contact with the eyes, rinse them immediately with cold water and then with eyewash solution if possible. Your eye may sting. Wash your hands after using Staphiderm Cream (unless you are using the preparation to treat your hands).

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

Adhere to the treatment as recommended by the physician. Even if there is an improvement in your health, do not stop treatment with this medicine without consulting your physician.

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

If you have any further questions about using this medicine, consult your physician or pharmacist.

4. Side effects

Like with all medicines, using Staphiderm Cream may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Contact a physician immediately if you suffer from any of the following side effects: allergic reaction (a rare side effect which appears in 1 user out of 1,000), difficulty breathing, tingling or swelling of the lips or mouth, swelling of the face or throat, severe skin rash.

Additional side effects

If additional less serious side effects occur, contact your physician as soon as possible.

Uncommon side effects (affect 1-10 users out of 1,000):

- Rash or itch
- Redness of the skin
- Contact dermatitis or eczema (itchy red rash with sensation of heat and swelling in the area where the cream is used)
- Pain, irritation (stinging) or burning in the area where the cream is used.

Rare side effects (affect 1-10 users out of 10,000):

- Itchy and watery eyes
- Swelling of the face, lips, mouth, throat or tongue which may cause difficulties in swallowing or breathing
- Hives or blisters

These side effects may also occur in children who use the medicine.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your physician.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

You can also report to the email: safety@trima.co.il

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a physician.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- The medicine can be used for 1 month after first opening.
- Storage conditions:** Store at a temperature below 25°C.

6. Additional information

In addition to the active ingredient, this medicine also contains:

liquid paraffin, cetostearyl alcohol, white soft paraffin, macrogol cetostearyl ether, sodium dihydrogen - phosphate dihydrate, chlorocresol, sodium hydroxide, purified water.

What the medicine looks like and content of the pack:

An aluminum tube containing white to off-white cream.

Package sizes: 15 or 30 grams.

Not all package sizes may be marketed.

Manufacturer's and Registration Holder's name and address: Trima Israel Pharmaceutical Products Maabarot Ltd., Maabarot 4023000, Israel.

This leaflet was revised in February 2023 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 148-97-33238-01

022330

Maabarot 4023000
Israel Pharmaceutical Products
Maabarot Ltd.

