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

The medicine is dispensed with a doctor's prescription only

STAPHIDERM CREAM

The active ingredient and its concentration: Fusidic Acid 2%

Inactive ingredients: see section 6 "Further information".

Read the package insert carefully in its entirety before using the medicine.

This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

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

Staphiderm Cream is an antibiotic preparation for local treatment, intended for the treatment of bacterial skin infections susceptible to the preparation.
You should notice an improvement after a few days of using Staphiderm. If there is no improvement after seven days, stop using the preparation and refer to the doctor. The duration of use of the preparation is usually up to two weeks; consult the doctor with regard to use for a longer period, as use of the cream for a prolonged period or in large quantities, may cause resistance of the bacteria to the treatment, to increased risk of side effects worsening and also to increased skin sensitivity to the medicine.
If the doctor told you to use Staphiderm on facial skin, avoid contact with the eyes.

1. WHAT IS THE MEDICINE INTENDED FOR?

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

2. BEFORE USING THE MEDICINE

☒ Do not use the preparation if:
- you are sensitive (allergic) to the active ingredient or to any of the other ingredients contained in the medicine (see section 6).

Special warnings regarding use of this medicine:
- **Do not use the medicine without consulting the doctor before starting treatment if** you are pregnant, suspect you are pregnant or are breastfeeding.
- If you are sensitive to any food or medicine, especially to antibiotic agents, inform the doctor before using the medicine.

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. It is particularly important to inform the doctor or pharmacist if you are using other preparation(s) for external use.

Pregnancy and breastfeeding:

Do not use the medicine without consulting the doctor before starting treatment if you are pregnant, suspect you are pregnant or are breastfeeding.

Driving and use of machines:

This medicine does not usually affect the ability to drive or operate machines. Nevertheless, if you experience a side effect that may impair your ability to drive or operate machines, consult the doctor.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions.

If you are unsure about how to use it, consult the doctor or pharmacist.
- The dosage and treatment regimen will be determined by the doctor only. Unless instructed otherwise by the doctor:
- Clean the treated area before use. With clean hands, rub the cream into the affected area 3-4 times a day for a period that does not exceed two weeks. Wash your hands after use (unless the treated area is the hands).
- If the doctor has instructed you to bandage the affected area, the frequency of daily use will be lower.
- You should notice an improvement after a few days of using Staphiderm. If there is no improvement after seven days, stop using the preparation and refer to the doctor. The duration of use of the preparation is usually up to two weeks; consult the doctor regarding use for a longer period. Prolonged use may cause bacterial resistance to the preparation.
- If the doctor has instructed you to use Staphiderm on facial skin, avoid contact with the eyes. If the preparation accidentally came into contact with the eyes, wash immediately with cold water and then, if possible, wash with an eye rinse solution. The eye may burn. If you experience pain or a vision disturbance, refer to the doctor immediately.
- Do not exceed the recommended dose.
- Do not swallow! This medicine is intended for external use only.

If you take an overdose or if a child accidentally swallowed the medicine, refer immediately to the doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to apply this medicine at the specified time, apply it as soon as you remember and after that, continue using at the usual specified time.

How can you contribute to the success of the treatment?
- Follow the treatment as recommended by the doctor.
- Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor or pharmacist.
- If there is no improvement in your condition within one week, refer to the doctor again.
- 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 doctor or pharmacist.

4. SIDE EFFECTS:

As with all medicines, use of Staphiderm may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Stop treatment with the medicine and refer to the doctor immediately if an allergic reaction develops, whose symptoms are: breathing difficulty, tingling or swelling of the lips and mouth, face or throat, severe skin rash.

Additional side effects:
- **Side effects that occur frequently are** skin reactions, primarily at the cream application site:
- Rash
- Itching
- Contact dermatitis (a red and itchy rash on the skin accompanied by a sensation of heat and swelling in the area where the cream was used)
- Sensation of pain
- Tingling, burning and/or redness in the area where the preparation was used
- **Side effects that occur infrequently:**
- Itchy or tearing eyes
- Conjunctivitis
- **Side effects of unknown frequency:**
- Eczema
- Redness of the skin
- Hives (urticaria)
- Swelling of the eyelids or other parts of the body.

If any of the side effects worsens or if you experience a side effect not mentioned in the leaflet, consult the doctor.

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

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

5. HOW SHOULD THE MEDICINE BE STORED?
- Avoid poisoning! This medicine and all other medicines should be stored in a safe place out of the reach of children and/or infants in order to prevent poisoning. Do not induce vomiting without explicit instruction from a doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- After first opening, can be used for one month.
- Store at a temperature below 25°C.

6. FURTHER INFORMATION
- In addition to the active ingredient, the medicine also contains inactive ingredients: Liquid paraffin, cetostearyl alcohol, white soft paraffin, macrogol cetostearyl ether, sodium dihydrogen - phosphate dihydrate, chlorocresol, sodium hydroxide, purified water.
- **What does the medicine look like and what are the contents of the package?** The package contains a tube of 15 g/30 g of a white-cream colored cream.
- **Manufacturing site:** Ben Shimon Florish Ltd., Industrial Park Misgav 20174 **for Manufacturer and License holder:** Trima, Israel Pharmaceutical Products Maabarot Ltd., Maabarot 4023000.

This leaflet was checked and approved by the Ministry of Health in December 2012

The registration number of the medicine in the National Drug Registry of the Ministry of Health: 148.97.33238.00

Maabarot 4023000
Israel Pharmaceutical Products
Maabarot Ltd.

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