PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Mupirocin Teva

Skin ointment

Composition

Mupirocin 2%

Additional ingredients are listed in section 6 "Additional information".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the 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?

Mupirocin Teva is used for treatment of skin infections, such as:

– Infection of hair follicles which forms suppurating wounds (folliculitis).
– An infectious skin infection with blisters and crust called impetigo.
– Recurrent suppurating wounds (furunculosis).

This ointment is intended for external use on your skin only.

Therapeutic class: Local antibiotics.

2. Before using the medicine

Do not use this medicine:

- If you are sensitive (allergic) to Mupirocin or any of the additional components the medicine contains (listed in section 6).

Do not use if the above applies to you. If you are not sure, do not use this medicine. Speak to your doctor or pharmacist before using Mupirocin Teva.

- Do not use Mupirocin Teva in the eyes, nose or around an intravenous tube ("IV").

Special warnings regarding the use of the medicine

- Mupirocin Teva may cause allergies or severe skin reactions. See "Side effects" in section 4.
- Do not use this medicine frequently or for a prolonged period of time without consulting the doctor - a fungal infection may develop if Mupirocin Teva is used for a prolonged period of time. If this happens, inform the doctor or pharmacist.

Avoid contact of the medicine with your eyes.

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

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

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you might be pregnant or are planning to become pregnant, contact your doctor or pharmacist for consultation before using this medicine.

When treating cracked nipple, the ointment should be removed by thorough washing prior to breastfeeding.

Driving and operating machinery

It is unlikely that Mupirocin Teva will affect your ability to drive or operate machinery.

Important information about some of the ingredients of the medicine

Mupirocin Teva contains polyethylene glycol. Speak with your doctor 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 doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.

Use of the medicine

Mupirocin Teva should not be mixed with other topical medicines in cream or ointment form on the infected area in your skin, as this may reduce the effectiveness of Mupirocin Teva.

The dosage and treatment regimen will be determined only by the doctor. The generally accepted dosage is:

Application of Mupirocin Teva to the skin twice to three times per day.

1. Wash and dry your hands.
2. Apply the ointment to the infected area in your skin.
3. You can cover the treated area with bandaid(s) or appropriate bandage(s), unless your doctor told you to leave it exposed.
4. Replace the cap onto the tube and wash your hands.

Do not exceed the recommended dose.

Duration of treatment

Use Mupirocin Teva for as long as the doctor instructed you. If you are unsure, ask your doctor or pharmacist. Bacteria usually disappear from the skin within 10 days of starting the treatment. Do not use Mupirocin Teva for more than 10 days. Discard what remains of the ointment.

Do not swallow!

This medicine is intended for external use only.

If you accidentally swallowed the ointment, consult your doctor or pharmacist.

If a child swallowed this medicine by mistake, immediately go to the doctor or the emergency room of the hospital and bring the package of the medicine with you.

If you forgot to use Mupirocin Teva

If you have forgotten to apply Mupirocin Teva, apply it as soon as you remember.

If your next dose should be applied within the hour, skip the missed dose.

Do not administer a double dose in order to compensate for a forgotten dose.

Follow the treatment as recommended by the doctor.

If you stop using Mupirocin Teva

If you stop using Mupirocin Teva too early, it is possible that not all of the bacteria have been destroyed or they may continue to multiply. Ask your doctor or pharmacist when to stop using the ointment.

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

If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, using Mupirocin Teva 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 using this medicine and refer to a doctor immediately in cases of:

Allergic reactions or severe skin reactions - these are very rare in patients using Mupirocin Teva. Signs include:

- Raised itchy rash.
- Swelling, sometimes in the area of the face or mouth, which causes breathing difficulties.
- Collapsing or loss of consciousness.

If you experience any of these symptoms, **refer immediately to your doctor** and stop using Mupirocin Teva.

If you develop a severe skin reaction or an allergy:

- Wash the ointment off.
- Stop using the ointment.
- Contact your doctor as soon as possible.

In rare cases, medicines such as Mupirocin Teva may cause an inflammation of the colon, known as pseudomembranous colitis, which causes diarrhea that is usually accompanied by blood and mucus, abdominal pain and fever.

Contact the doctor as soon as possible if you are experiencing any of these symptoms.

The following side effects may occur when using this medicine:

Common side effects (may occur in up to 1 of every 10 patients)

- A burning sensation where the ointment is applied.

Uncommon side effects (may occur in up to 1 of every 100 patients)

- Itching, redness, tingling and dryness on your skin where Mupirocin Teva ointment is applied.
- Allergic rash, itching, redness or skin pain may also occur in other parts of your body.

Very rare side effects (may occur in up to 1 of every 10,000 patients)

- Swollen face and/or breathing difficulties. This may be a sign of a severe allergic reaction which may require an 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 your doctor.

Reporting side effects

Side effects may be reported to the Ministry of Health by clicking on the link "report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: https://sideeffects.health.gov.il

5. How to store the medicine?

Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning.

Do not induce vomiting without an explicit instruction from the 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 the tube, the ointment may be used for up to 6 months, but not after the expiry date.

Store below 25°C.

Mupirocin Teva is a homogeneous ointment, do not use it if it seems different than usual.

6. Additional information

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

Polyethylene glycol 400, Polyethylene glycol 3350

What does the medicine look like and what are the contents of the package

Each pack contains a tube of 15 grams homogeneous ointment.

Name and address of marketing authorization holder and manufacturer

Teva Israel Ltd.

124 Dvora HaNevi'a St., Tel Aviv 6944020

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

113.77.29505

The leaflet was revised in March 2022 in accordance with the Ministry of Health guidelines.

teva