



Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

The dispensing of this medicine requires a doctor's prescription

Cicloderm Cream / Solution

Active ingredient: Ciclopirox olamine 1%

Inactive ingredients in the medicine - see section 6 'Additional information'.

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have further questions, refer to your 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 to you that their medical condition is similar to yours.

The safety of using this medicine in children under 10 years old has not been established.

If your condition does not improve within 30 days, consult your doctor.

1. What is this medicine intended for?

Broad-spectrum antifungal medicine for local treatment of skin fungi.

Therapeutic group: antifungal.

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 that this medicine contains (see Section 6).

⚠ Special warnings about using this medicine:

If you are pregnant or breast-feeding, **do not use this medicine without consulting your doctor first.**

Additional warnings:

- If you are sensitive to any food or medicine, tell your doctor before you start using Cicloderm.
- Do not use occlusive dressings.
- Cicloderm Cream contains paraffin which may cause latex condoms to break or leak, so avoid using this cream together with such condoms.

If you are taking or have recently taken other medicines, including nonprescription medicines and nutritional supplements, tell your doctor or pharmacist.

Pregnancy and breastfeeding

If you are pregnant or breast-feeding, consult a doctor before taking this medicine.

Smoking

Cicloderm Solution: Do not light cigarettes or expose yourself to flames until the solution has dried completely.

3. How to use this medicine?

Always use according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure how to use this medicine.

Only your doctor will determine your dose and how you should take the medicine. Persist with your treatment as recommended by the doctor.

In the absence of other instructions from your doctor, use as follows: apply the cream or spray the solution on and around the affected area and massage gently. Repeat twice a day, in the morning and in the evening. Continue this treatment until signs of the fungal infection have disappeared, and for another week or two after that, to prevent it from coming back.

The Cicloderm Solution package contains an additional nozzle to be used if your doctor has instructed you to do so.

If your condition does not improve within 30 days, consult your doctor.

Do not exceed the recommended dose.

Do not swallow, for external use only. Avoid contact with the eyes. Not for vaginal application.

How can you contribute to the success of the treatment?

Complete the course of treatment as recommended by your doctor. Fungi thrive in moist conditions, so keep the affected area dry. Always wash the affected area before you apply the medicine. Between applications, you may use talcum powder or an antifungal powder to dry the area. When treating feet, wash thoroughly and dry carefully, especially between your toes. Cotton socks are preferable; avoid socks made of wool or synthetic materials. It is advisable to change your socks several times a day (depending on how much you sweat). When the season allows it, wearing sandals without socks is advisable.

If you have taken an overdose, or if a child has accidentally swallowed some of this medicine, go immediately to a hospital emergency room and bring the medicine package with you.

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

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

4. Side effects

Like all medicines, using Cicloderm may cause side effects in some people. Do not be alarmed by this list of side effects. You may not experience any of them.

Consult your doctor as soon as possible if you develop a local irritation, inflammation or rash in the treated area.

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

Reporting side effects

You can report side effects to the Ministry of Health (MoH) by following the link 'Reporting Side Effects of Medication' on the MoH home page (www.health.gov.il) which links to an online form for reporting side effects. You can also follow this link: <https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

You can also report side effects by email to: 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 reach of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package/label. The expiry date refers to the last day of that month.
- In a cool place below 25°C.
- Cicloderm Solution: Do not light cigarettes or expose yourself to flames until the solution has dried completely.

6. Additional information

- In addition to the active ingredient this medicine also contains the following inactive ingredients:

Cream:

2-octyldodecanol, Liquid paraffin, Stearyl alcohol, Cetyl alcohol, Cocamide DEA, Polysorbate 60, Myristyl alcohol, Sorbitan monostearate, Benzyl alcohol, Lactic acid, Purified water.

Solution:

Polyethylene glycol 400, Propylene glycol, Isopropanol, Lactic acid, Purified water.

- **What the medicine looks like and what are the contents of the package -** Each package of Cicloderm Cream contains a 15g tube of ivory-white cream. Each package of Cicloderm Solution contains a 30ml bottle with a colorless to yellowish liquid.
- **Manufacturer and registration holder:** Trima Israel Pharmaceutical Products Maabarot Ltd, Maabarot 4023000, Israel.
- **This leaflet was reviewed and approved by the Ministry of Health in:** April 2017
- **Registration number of the medicine in the National Drug Registry of the Ministry of Health:**
Cicloderm Cream: 062.23.26751.00, Cicloderm Solution: 136.35.28781.00