

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

This medicine is dispensed with a doctor's prescription only

Ciclocloderm C Cream

Active ingredients:

clobetasone butyrate	0.05%
ciclopirox olamine	1%
gentamicin (as sulfate)	0.1%

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 you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult 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.

1. What is this medicine intended for?

Ciclocloderm C is used for local treatment of skin inflammations accompanied by a mycotic and/or bacterial infection.

Therapeutic group:

Clobetasone - corticosteroid, helps reduce swelling and irritation.

Ciclopirox - antifungal.

Gentamicin - an antibiotic in the aminoglycoside class.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to any of the active ingredients or to any of the other ingredients in this medicine (see section 6).
- To treat any of the following skin problems, because it could make them worse:
 - viral skin infection (unless the infection is being treated with an anti-infective medicine at the same time)
 - acne
 - severe flushing of skin on and around your nose (rosacea)
 - itchy skin which is not inflamed

Special warnings about using this medicine

Before using Ciclocloderm C, tell your doctor if:

- you have previously had an allergic reaction with another steroid.
- using around a chronic leg ulcer as you may be at increased risk of local allergic reaction or infection.
- you have been advised by your doctor to use this medicine under an occlusive dressing (including a child's diaper). Make sure that the skin is cleansed before a fresh dressing is applied to prevent infections. Occlusive dressings (including a child's diaper) make it easier for the active ingredient to pass through the skin, making it possible to accidentally use too much.
- you are applying the medicine to thin skin such as the face, as skin is thinner and may absorb larger amounts of the medicine. Dressings or bandages should not be used on the face where the cream is applied.
- you are applying the cream to the face over a long period of time as it may cause skin thinning.

- you are applying the cream on broken skin or within the skin folds.
- you are applying near eyes or on eyelids, as cataracts or glaucoma may result if the cream repeatedly enters the eye.
- if an infection develops (see section 4, Side effects).
- The use of topical antibiotics (the ingredient gentamicin) occasionally allows overgrowth of organisms that are not susceptible to antibiotics, including fungi. If this occurs, or if irritation, sensitization, or superinfection develops, treatment with the medicine should be discontinued and alternative therapy instituted.

Contact your doctor if you have blurred vision or other visual disturbances.

If there is a worsening of your condition during use, consult your doctor – you may be experiencing an allergic reaction, have an infection or your condition may require a different treatment.

If you experience a recurrence of the disturbance shortly after stopping treatment, within 2 weeks, do not restart using the cream without consulting your doctor unless your doctor has previously advised you to do so. If the disturbance has resolved and on recurrence the redness extends beyond the initial treatment area and you experience a burning sensation, seek medical advice before restarting treatment.

Children and adolescents

Safety of using the medicine in children below the age of 10 years has not been established.

If you are not sure if any of the things described above applies to you, contact your doctor or pharmacist before using this medicine.

Interactions with other medicines

If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking medicines that contain ritonavir and itraconazole.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, consult your doctor or pharmacist before taking this medicine.

If you are using Ciclocloderm C while breast-feeding, do not apply the cream to the breast area to prevent the cream from accidentally reaching the infant's mouth.

Important information about some of this medicine's ingredients

Ciclocloderm C contains chlorocresol and cetostearyl alcohol.

Ciclocloderm C cream contains chlorocresol which may cause allergic reactions and cetostearyl alcohol which may cause local skin reactions (e.g. Contact dermatitis).

Whilst using Ciclocloderm C do not smoke or go near naked flames due to the risk of severe burns.

Fabric (clothing, bedding, dressing, etc.) that has been in contact with this medicine burns more easily and is a severe fire hazard. Washing clothing and bedding may reduce build-up of the medicine but not totally remove it.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine. The

recommended dosage is usually:

Apply a thin layer to the affected area twice and, if necessary, up to three times a day. When there is improvement, the frequency of use may be reduced.

Do not exceed the recommended dose.

Your condition does not improve within several days or if the condition worsens, contact your doctor again.

Do not use the medicine for more than 7 days unless your doctor has instructed you otherwise.

Avoid the use of occlusive dressings on the affected area (disposable diapers are considered occlusive dressings), unless your doctor has instructed you to.

Do not swallow. For external use only.

If you apply Ciclocloderm C to your face

You should only apply the cream to your face if your doctor tells you to. The cream should not be used for too long as the skin on your face thins easily. **Do not let the cream get into your eyes.**

If you use more Ciclocloderm C than you should

If you apply a lot or if a lot is accidentally swallowed, it could make you ill. Talk to your doctor or go to hospital as soon as possible.

If you have accidentally swallowed a large amount of Ciclocloderm C, rinse your mouth with a large quantity of water and immediately consult with your doctor or pharmacist.

If you forget to use Ciclocloderm C

If you forget to apply your cream, apply it as soon as you remember. If it is close to the time you are next meant to apply it, wait until this time.

Adhere to the treatment as recommended by your doctor.

If you stop taking Ciclocloderm C

If you use Ciclocloderm C regularly, it is important that you talk to your doctor before you stop using it, as your condition may get worse if you stop use suddenly.

Do not take medicines in the dark! Check the label and the dose every time you take medicine. Wear glasses if you need them. If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

As with any medicine, using Ciclocloderm C may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

Stop using Ciclocloderm C and inform your doctor immediately if:

- you feel that your skin condition gets worse, you develop a generalised rash, redness, itching, a feeling of burning, blistering or if your skin becomes swollen during treatment. You may be allergic to the cream, have an infection or need other treatment.

Additional side effects:

Very rare side effects (may affect up to 1 in 10,000 users):

- an increased risk of skin infection
- an allergic skin reaction where the cream is applied
- a feeling of burning, irritation, itching or pain where the cream is applied
- rash, itchy bumpy skin or redness of the skin
- increased hair growth and changes in skin colour
- thinning of your skin and it may also damage more easily
- weight gain, rounding of the face
- delayed weight gain or slowing of growth in children

- bones can become thin, weak and break easily
- cloudy lens in the eye (cataract) or increased pressure in eye (glaucoma)
- increased blood sugar levels or sugar in the urine
- high blood pressure
- a decrease in the level of the hormone cortisol in your blood

Side effects of unknown frequency (the frequency of these effects has not been established yet)

- blurred vision
- steroid withdrawal reaction: Following continuous use for prolonged periods, a withdrawal reaction may occur on stopping treatment accompanied by some or all of the following features: redness of the skin which can extend beyond the initial area treated, a burning or stinging sensation, intense itching, peeling of the skin, oozing open sores.

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 doctor.

You can report side effects to the Ministry of Health by following the 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page (www.health.gov.il), which opens an online form for reporting side effects or you can also use this link:

<https://sideeffects.health.gov.il>

You may also report to e-mail: 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 your doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package/label. The expiry date refers to the last day of that month.

Storage conditions

- Store in a cool place, below 25°C.

6. Additional information

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

Purified water, glycerol, glyceryl monostearate, propylene glycol, cetostearyl alcohol, beeswax (white), self-emulsifying glyceryl monostearate (acid stable), dimethicone, citric acid, chlorocresol.

What the medicine looks like and contents of the pack:

A white to off-white homogenous cream packed in a tube that contains 15 g or 30 g.

Not all pack sizes may be marketed.

Manufacturer and registration holder's name: Trima Israel Pharmaceutical Products Maabarot Ltd., Maabarot 4023000.

Revised in February 2024 according to Ministry of Health guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 068-06-27821-00

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Maabarot 4023000
Israel Pharmaceutical Products
Maabarot Ltd.

