

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

The medicine is dispensed with a doctor's prescription only

Clobetasol Propionate-Trima Cream

The active ingredient and its concentration:

Clobetasol Propionate 0.05%

Inactive ingredients: See section 6 "Further Information".

Read the leaflet 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 to treat your ailment. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Clobetasol Propionate-Trima Cream is intended for topical treatment of skin inflammations and itching responsive only to potent corticosteroids.

Therapeutic group: Potent corticosteroids.

2. BEFORE USING THE MEDICINE

⚠ Do not use this preparation:

- if you are in the first trimester of pregnancy.
- if you are sensitive (allergic) to the active ingredient or to any of the other ingredients contained in the medicine (see section 6).
- for treatment of acne vulgaris, inflammations around the mouth, viral infections, such as chicken pox or herpes.
- for treatment of bacterial infections, including dermal tuberculosis, or fungal skin infections, itching of the genitals or the anus.
- in children under one year of age.
- for treatment of skin diseases, such as rosacea (severe redness of the facial skin) or a red rash in the mouth and chin area (perioral dermatitis).

⚠ Do not use the medicine without consulting a doctor before commencing treatment:

- if you are suffering, or have suffered in the past, from impaired function of the immune system, tuberculosis.
- if you have diabetes.

⚠ Special warnings regarding use of the medicine:

- Do not use on extensive areas of the skin or on open or infected wounds.

- If you have psoriasis, you should be under close and frequent medical surveillance.
- If you are using the cream under an occlusive dressing or a child's diaper: an occlusive dressing facilitates the active ingredient absorption through the skin and thus may accidentally end up in usage of a dosage of the cream that is too high.
- Prolonged use on the facial skin is not recommended.
- Do not use frequently or for a prolonged period without consulting a doctor. When using the preparation for a prolonged period, inform the doctor if you have glaucoma or a cataract.
- Special caution is required when used in children and adolescents.
- If you are sensitive to any food or medicine, inform the doctor before taking the medicine.

⚠ If you are taking other medicines including nonprescription medicines and nutritional supplements, inform the doctor or pharmacist. Especially inform the doctor or pharmacist if you are taking other preparations for external use.

⚠ Pregnancy and breastfeeding

Do not use the preparation if you are in the first trimester of pregnancy.

Consult a doctor before commencing treatment if you are pregnant (in the second or third trimester), are planning to become pregnant or are breastfeeding.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure.

Do not exceed the recommended frequency and duration of treatment.

Unless instructed otherwise by the doctor:

Clean the treated area before use.

With clean hands, gently apply, one to two times a day, a small amount of the cream onto the affected area. With improvement, the number of applications can be reduced to once a day, or less frequently. After applying, wash your hands thoroughly, unless the preparation is intended to treat the hands.

Adhere to the treatment recommended by the doctor. If there is no improvement in your condition within one week, refer to the doctor again.

Unless indicated otherwise by the doctor, do not use the preparation on the facial skin for a period exceeding 5 days.

Unless indicated otherwise by the doctor, avoid use of occlusive dressing in the affected area (disposable baby diapers are occlusive dressings). The course of treatment for a child is usually not more than 5 days - unless the doctor has told you to use the cream for longer. The doctor

may want to see the child every week whilst using the cream.

Do not swallow! For external use only!

Be careful not to let the medicine get into the eyes and mucosal tissues. In case of contact, wash thoroughly with water.

If you accidentally took a higher dosage, or if a child has accidentally swallowed the medicine, immediately refer 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 on time, apply it as soon as you remember. If it is almost time for the next application, wait and apply it at that time.

Even if there is an improvement in your health, do not discontinue treatment with this medicine without consulting the doctor or pharmacist.

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

4. SIDE EFFECTS

As with any medicine, use of Clobetasol Propionate-Trima Cream 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.

Discontinue treatment and refer to the doctor immediately if:

- an allergic reaction develops: swelling of the eyelids, face or lips.
- your skin problem gets worse.

Additional side effects:

- A sensation of heat, irritation or itching in the treated area.
- If you have psoriasis, raised bumps with pus may develop under the skin during or after treatment. This effect is known as pustular psoriasis.

Refer to the doctor as soon as possible if the following side effects develop (very rare, as a result of prolonged/extensive use or with an occlusive dressing):

- Cushing's syndrome, manifested by a round face, hypertension, weight gain, slowed growth in children, acne. This effect is more common in infants and children.

Side effects occurring as a result of prolonged/extensive use/with an occlusive dressing (such as baby diapers):

- Dilatation of blood vessels under the skin.
- Thinning of the skin (the skin becomes thinner and more vulnerable).
- Stretch marks in the skin.
- Excessive hair growth.

- Change in skin pigmentation.
- Contact dermatitis.

If any of the side effects worsen, or if you are suffering from a side effect not mentioned in the leaflet, consult the doctor.

Side effects in children

Parents must inform the attending doctor of any side effect and of any other medicine being given to the child!

See above for details of special side effects and drug interactions.

5. HOW SHOULD THE MEDICINE BE STORED?

- Store in a cool place, at a temperature below 25°C.
- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach of children and/or infants to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.
- Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- The medicine can be used for 120 days after first opening of the tube.

6. FURTHER INFORMATION

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

Propylene glycol, purified water, glyceryl monostearate, cetostearyl alcohol, glyceryl stearate (and) PEG-100 stearate, synthetic beeswax, chlorocresol, trisodium citrate and citric acid anhydrous.

• What does the medicine look like and what are the contents of the pack?

Each package contains a tube which contains a white-colored cream weighing 25 grams.

• Manufacturer and license holder: Trima Israel Pharmaceutical Products Maabarot Ltd., Maabarot 4023000, Israel.

This leaflet was checked and approved by the Ministry of Health in December 2013.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 150.92.33656.00

Maabarot 4023000
Israel Pharmaceutical Products
Maabarot Ltd.

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