

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986
The medicine is dispensed according to a physician's prescription only

Clobetasol Propionate - Trima Cream

Clobetasol propionate 0.05% w/w
Each gram contains 0.5 mg of clobetasol propionate.

Inactive ingredients and allergens: See section 2 "Important information about some of the ingredients of the medicine" and section 6 "Additional 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, contact the physician 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.

The medicine is not intended for children under 1 year of age.

1. WHAT IS THE MEDICINE INTENDED FOR?

Clobetasol Propionate - Trima Cream is used to reduce redness and itchiness of certain skin problems. These skin problems include:

- Recurrent eczema.
- Psoriasis - thickened patches of inflamed, red skin, often covered by silvery scales, excluding widespread plaque psoriasis.
- Lichen planus (a skin disease that causes itchy, reddish-purple, flat bump on the wrists, forearms or lower legs).
- Discoid lupus erythematosus (a disease of the skin most often affecting the face, ears and scalp, and causing scarring and increased sensitivity of the skin to sunlight).
- Dermatitis and other skin conditions that do not respond to milder steroid ointments or creams.

Therapeutic group: Corticosteroids.
A group of medicines called steroids that help reduce swelling and irritation.

2. BEFORE USING THE MEDICINE

Do not use the medicine:

- If you are sensitive (allergic) to clobetasol propionate or to any of the additional ingredients contained in the medicine (as listed in section 6)
- In children under 1 year of age
- To treat any of the following skin problems; it could make them worse:
 - acne
 - severe flushing of skin on and around your nose (rosacea)
 - spotty red rash around the mouth (perioral dermatitis)
 - itching around the anus or genitals (penis or vagina)
 - infections of the skin [viral, fungal or bacterial (unless the infection is being treated with an anti-infective medicine at the same time)]
 - itchy skin which is not inflamed
 - widespread plaque psoriasis, except for single lesions.

Do not use the medicine if any of the above apply to you. If you are not sure, talk to your physician or pharmacist before using Clobetasol Propionate - Trima Cream.

Special warnings regarding the use of the medicine
Before treatment with Clobetasol Propionate - Trima Cream, tell your physician if:

- You experience newly developed bone pain or worsening of previous bone symptoms during treatment with Clobetasol Propionate - Trima Cream, especially if you have been using Clobetasol Propionate - Trima Cream for a long time or have used it repeatedly.
- You use other oral/topical medications containing corticosteroids or medications intended to regulate your immune system (e.g., for autoimmune disease or after a transplantation). Combining Clobetasol Propionate - Trima Cream with these medicines may cause serious infections.
- You have previously had an allergic reaction to another steroid.
- You are applying the cream under an airtight dressing, including a child's nappy. These dressings make the absorption of the active ingredient through the skin easier and therefore may accidentally lead to use of too high a dosage of the cream.
- To prevent infections, make sure the skin is clean before putting on a new dressing.
- You are applying the cream on cracked or damaged skin or within skin folds.
- You are applying the cream over a large surface area.
- You have psoriasis; your physician will want to see you more often.
- You are using the medicine to treat around a chronic leg ulcer, since you may be at increased risk of a localized allergic reaction or infection.
- You are applying Clobetasol Propionate - Trima Cream near the eyes or on the eyelids, as cataract or glaucoma may result if the cream repeatedly enters the eye.
- You are applying Clobetasol Propionate - Trima Cream to thin skin such as the face, since Clobetasol Propionate - Trima Cream can cause thinning of the skin. Use of Clobetasol Propionate - Trima Cream on the face should be limited to 5 days. Do not use dressings or bandages on the skin of the face where the cream was applied. Contact your physician if you experience blurred vision or other visual disturbances.

If there is a worsening of your condition during use, consult your physician. You may be experiencing an allergic reaction, have an infection or your condition requires a different treatment. If an infection develops while using the medicine, consult with a physician or pharmacist. If you are not sure if any of the above apply to you, talk to your physician or pharmacist before using this medicine.

If you experience a recurrence of your condition shortly after stopping treatment, within 2 weeks, do not restart using the cream without consulting a physician or pharmacist. If your condition 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

- Do not use this medicine in children under 1 year of age.
- Avoid prolonged use in children and infants over 1 year of age, as their skin is thinner than that of adults and, as a result, may absorb a larger amount of the medicine.
- Treatment duration in children is up to 5 days – unless the physician instructs otherwise. The treatment may be accompanied by a weekly examination by the attending physician.
- In children, do not use dressings and bandages where the cream has been applied.

Drug interactions
If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the physician or pharmacist. Especially if you are taking ritonavir or itraconazole.

Pregnancy and breastfeeding
If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult your pharmacist or physician before taking this medicine. If you are using Clobetasol Propionate - Trima Cream while breastfeeding, do not apply the cream on the breast area, to avoid a situation in which the cream accidentally reaches the baby's mouth.

Important information about some of the ingredients of the medicine
Clobetasol Propionate - Trima Cream contains 475 mg propylene glycol per gram of product, cetostearyl alcohol and chlorocresol. Propylene glycol may cause skin irritation. Cetostearyl alcohol may cause local skin reactions (e.g., contact dermatitis). Chlorocresol may cause allergic reactions. Whilst using Clobetasol Propionate - Trima Cream 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 product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the physician's instructions. Check with the physician or the pharmacist if you are uncertain about the preparation dosage and treatment regimen. The dosage and treatment regimen will be determined only by the physician. The recommended dosage is generally:

- Application of a thin layer of Clobetasol Propionate - Trima Cream once or twice a day. The dosage may be reduced as the condition of the skin begins to get better, or stopped when it improves. Your physician may prescribe a weaker steroid for you instead.
- If you are also using a moisturizer, wait a while to allow Clobetasol Propionate - Trima Cream to be absorbed into the skin before applying the moisturizer.
- This cream is for use on your skin only.
- Do not use this cream for more than 4 weeks without consulting your physician. If you need to be treated for a long time, your physician may decide that you need to use a milder cream or ointment.
- If your skin problem worsens or does not improve within two to four weeks, consult the physician.
- The germs that cause infections thrive in warm and moist conditions that exist under dressings; therefore, if you have been instructed to cover the treated area with a dressing, always clean the skin before a fresh dressing is put on, to prevent infection of the skin under the dressing.
- If you are applying the cream on someone else, make sure you wash your hands after use or wear disposable gloves.

Do not exceed the recommended dose – especially in children. For external use only

Instructions for applying the cream

1. Wash your hands.
2. Apply a thin layer to the affected area(s) and gently rub until it has all been absorbed into the skin. You can measure how much Clobetasol Propionate - Trima Cream to use with your fingertip (as demonstrated in the illustration below). For children, you will

need to use less cream but still use an adult finger to measure a fingertip unit.



3. Unless you intend to apply the cream to your hands as part of the treatment, wash them again after using the cream.

Use in adults

Body area	Face and neck	Back	Abdomen and chest	One arm (not including the hand)	Both sides of one hand	One leg (not including the foot)	One foot
Fingertip units	2½	7	7	3	1	6	2

Do not worry if you find you need a little more or less cream than described above. It is only a rough guide.

Use in children from the age of 1 to 10 years

Number of adult fingertip units needed					
Child's age	Face and neck	Arm and hand	Leg and foot	Abdomen and chest	Back including buttocks
1-2 years	1½	1½	2	2	3
3-5 years	1½	2	3	3	3½
6-10 years	2	2½	4½	3½	5

Regarding use in children – see section 2 "Before using the medicine".

If you have psoriasis
If you have thick patches of psoriasis on your elbows or knees, your physician may suggest applying the cream under an airtight dressing. In this case, use an airtight dressing at night only to help the cream start working. After a short period of time, apply the cream as usual.

If you apply Clobetasol Propionate - Trima Cream to your face
You should only apply the cream to your face if your physician told you to. Limit use to 5 days only, as the skin of the face thins easily. **Do not use dressings or bandages on the skin of the face where the cream was applied.** **Do not let the cream get into your eyes.** If this happens, wash out the cream with plenty of water.

If you accidentally took a higher dosage
If you apply too much or if you accidentally swallowed the cream, you may become ill. Talk to your physician or go to a hospital as soon as possible.

If a child has accidentally swallowed the medicine, immediately contact a physician or go to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine
If you forget to apply the cream, apply it as soon as you remember. If it is close to the next time you should apply it, wait until this time. Do not apply extra Clobetasol Propionate - Trima Cream to make up for the forgotten dose. Adhere to the treatment as recommended

by the physician.
If you stop using the medicine
If you use Clobetasol Propionate - Trima Cream regularly, make sure to consult with your physician before you stop using it. Your condition may get worse if the treatment is stopped suddenly.

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 the use of the medicine, consult the physician or the pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Clobetasol Propionate - Trima Cream may cause side effects in some of the users. Do not be alarmed by reading the list of side effects. You may not suffer from any of them. **Stop using Clobetasol Propionate - Trima Cream and immediately contact the physician if:**

- You find that the condition of your skin is getting worse, you develop a generalized rash or your skin becomes swollen during treatment. You may be allergic to the cream, have an infection or need other treatment.
- You have psoriasis and bumps with pus are developed under your skin. This may happen during or after the treatment and is known as pustular psoriasis.

Additional side effects you may notice when using Clobetasol Propionate - Trima Cream include:
Common side effects (may occur in up to 1 in 10 people)

- A feeling of burning, pain, irritation or itching where the cream is applied.

Uncommon side effects (may occur in up to 1 in 100 people)

- Thinning of the skin which may lead to stretch marks
- Blood vessels under the surface of your skin may become more noticeable.

Very rare side effects (may occur in up to 1 in 10,000 people)
Use of Clobetasol Propionate - Trima Cream for a long period of time, or use under an airtight dressing, may cause the following symptoms:

- Weight gain
- Moon-face, round face
- Obesity
- Skin thinning
- Skin wrinkling
- Skin dryness
- Changes in the color of the skin
- Increased body hair
- Hair loss/lack of hair growth/damaged hair appearance.

Additional very rare skin side effects that can occur:

- Allergic reaction at the site of application
- Worsening of the condition of the skin
- Application site irritation or pain
- Redness
- Rash or hives
- If you have psoriasis, bumps with pus under the skin may develop. This may happen very rarely during or after treatment and is known as pustular psoriasis.
- Skin infection
- Acne.

In children, pay attention to the following signs:

- Delayed weight gain
- Delayed growth.

Very rare side effects that may show up in blood test results or when your physician gives you a medical examination:

- A decrease in the level of the hormone cortisol in the blood
- Increased levels of sugar in the blood or urine
- High blood pressure
- Cloudy eye lenses (cataract)
- Increased pressure in the eye (glaucoma)
- Vision problems caused by detachment of the retina in the eye (central serous chorioretinopathy)
- Weakening of the bones through gradual loss of minerals (osteoporosis). Additional tests may be needed after the medical examination to diagnose this condition.

Side effects of unknown frequency (frequency was not yet determined)

- Blurred vision.
- Steroid withdrawal reaction: If the medicine was used continuously for a prolonged period, a withdrawal reaction may occur on stopping treatment, with some or all of the following features: redness of the skin which can extend beyond the initial area treated, a burning sensation, intense itching, peeling of the skin, oozing open sores.

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 with the physician.

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://sideeffects.health.gov.il>
In addition, you can also report to the email: safety@trima.co.il

5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the physician.
- 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.
- The medicine can be used for 4 months after initial tube opening, but no later than the expiry date.
- Store in a cool place below 25°C.
- Do not discard medicines in the wastewater or household waste. Ask the pharmacist how to dispose of medicines that are no longer in use. These measures will help protect the environment.

6. ADDITIONAL 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 the medicine looks like and the content of the package:** Each package contains an aluminum tube closed with a screw cap, containing 25 or 30 grams of white cream. Not all pack sizes may be marketed.
- **Manufacturer and registration holder:** Trima Israel Pharmaceutical Products Maabarot Ltd., Maabarot 4023000, Israel.

Revised in November 2022 according to MOH guidelines.
Registration No. of the medicine in the National Drug Registry of the Ministry of Health: 150.92.33656.00