

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

The medicine is dispensed according to a physician's prescription only

Dermovate Cream

clobetasol 17-propionate 0.05% w/w

Each gram contains 0.5 mg of clobetasol 17-propionate.

For the list of the inactive and allergenic ingredients in the medicine, see section 2 – “Important information about some of the ingredients in 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, refer to the physician 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.

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

1. WHAT IS THE MEDICINE INTENDED FOR?

Dermovate Cream is indicated for adults, elderly and children over 1 year for local short-term treatment only of more resistant inflammatory and pruritic manifestations of steroid responsive dermatoses that were unresponsive to previous steroid treatment.

These include the following conditions:

- Psoriasis, excluding widespread plaque psoriasis
- Recalcitrant dermatoses
- Lichen planus
- Discoid lupus erythematosus
- Other skin conditions that have not responded satisfactorily to previous steroid treatment.

Therapeutic group: Steroids.

2. BEFORE USING THE MEDICINE

Do not use the medicine:

- If you are sensitive (allergic) to clobetasol 17-propionate or to any of the additional ingredients contained in this medicine (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 and 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 if any of the above apply to you. If you are not sure, talk to your physician or pharmacist before using Dermovate Cream.

Special warnings regarding use of the medicine

Before the treatment with Dermovate Cream, tell the physician if:

- You experience newly developed bone pain or worsening of previous bone symptoms during treatment with Dermovate especially if you have been using Dermovate for a long time or have used it repeatedly
- You use other oral/topical medication containing corticosteroids or medication intended to regulate your immune system (e.g., for autoimmune disease or after a transplantation). Combining Dermovate 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 broken or damaged skin or within skin folds
- You are applying the cream over a large surface area
- You have psoriasis; in this case, your physician will want to see you more often
- You are using the medicine around a chronic leg ulcer, since you may be at increased risk of a localized allergic reaction or infection
- You are applying Dermovate Cream near the eyes or on the eyelids, as cataract or glaucoma may result if the cream repeatedly enters the eye
- You are applying Dermovate Cream to thin skin such as the face, since Dermovate Cream can cause thinning of the skin. Use of Dermovate 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 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/ointment 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, please 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 breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your physician for advice before using this medicine.

If you are using Dermovate Cream while breast-feeding, 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 in the medicine

Dermovate 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 Dermovate 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 pharmacist if you are uncertain about the preparation dosage and treatment regimen.

The dosage and treatment regimen will be determined by the physician only.

- The recommended dosage is usually application of a thin layer of Dermovate 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 Dermovate 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 Dermovate 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 are meant to apply the cream to your hands as a part of the treatment, wash them again after using the cream.

Use in adults

A line drawing of an adult human figure from the front. Lines point to the face, neck, back, front, one arm, both sides of one hand, one leg, and one foot.	<p>Face and neck: 2½ fingertip units.</p> <p>Back: 7 fingertip units.</p> <p>Front: 7 fingertip units.</p> <p>One arm (not including the hand): 3 fingertip units.</p> <p>Both sides of one hand: 1 fingertip unit.</p> <p>One leg (not including the foot): 6 fingertip units.</p> <p>One foot: 2 fingertip units.</p>
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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

Number of adult fingertip units needed					
Child's age	Face and neck	Arm and hand	Leg and foot	Front	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 normal.

If you apply Dermovate 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 have taken a higher dosage

If you apply too much or if accidentally swallowed, it could make you ill. Talk to your physician or go to a hospital as soon as possible.

If a child has accidentally swallowed the medicine, refer immediately to a physician or 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 time you are next meant to apply it, wait until this time.

Do not apply extra Dermovate Cream to make up for the missed dose.

Adhere to the treatment regimen recommended by your physician.

If you stop taking the medicine

If you use Dermovate Cream regularly, make sure to consult your physician before you stop using it. Your condition may get worse if 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 use of the medicine, consult the physician or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Dermovate Cream may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not suffer from any of them.

Stop using Dermovate Cream and refer immediately to 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 develop bumps with pus under the skin. This can happen during or after the treatment and is known as pustular psoriasis.

Additional side effects you may notice when using Dermovate Cream include:

Common side effects

These may affect up to 1 in 10 people:

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

Uncommon side effects

These may affect **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

These may affect **up to 1 in 10,000** people:

Use of Dermovate 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 to the color of the skin
- Increased body hair
- Hair loss/lack of hair growth/damaged looking hair.

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 can happen very rarely during or after treatment and is known as pustular psoriasis
- Skin infection
- Acne.

In children, also pay attention to the following signs:

- Delayed weight gain

- Slow growth.

Very rare side effects that may show up in blood test results or in medical examinations:

- 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 (side effects whose frequency was not yet determined)

- Blurred vision
- Steroid withdrawal reaction: If used over prolonged periods a withdrawal reaction, which might appear to be different from the previous condition, may occur in some patients during treatment or within days to weeks after stopping treatment, with 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 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.

Reporting side effects

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/>

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 unless explicitly instructed to do so by the physician.
- 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.
- Can be used for 3 months after first opening.
- Store below 25°C.
- Do not discard medicines in the wastewater or household waste bin. 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 (see section 2), glyceryl monostearate, cetostearyl alcohol (see section 2), arlacel 165, beeswax substitute 6621, chlorocresol (see section 2), sodium citrate, citric acid monohydrate and purified water.
- What the medicine looks like and the contents of the package: Each package contains a tube with a plastic screw cap, containing 25, 30 or 100 grams of cream.
Not all package sizes may be marketed.
- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Manufacturer: GlaxoSmithKline Trading Services Limited, Dublin, Ireland.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 059-85-22064.

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