

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

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

Dermovate Ointment

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 Ointment 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).
- on children under 1 year of age.
- for the treatment of any of the following skin problems; it could make them worse:
 - acne
 - severe flushing of the skin on and around the 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 simultaneously with an anti-infective medicine])
 - 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 Ointment.

Special warnings regarding use of the medicine

Before the treatment with Dermovate Ointment, 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 ointment under an airtight dressing, including a child's nappy. Such 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 ointment

- Make sure that the skin is clean before a fresh dressing is applied to prevent infections
- you are applying the ointment on cracked or damaged skin or within the skin folds
- you are applying the ointment over a large surface area of skin
- you have psoriasis; in this case your physician will want to see you more often
- you are using Dermovate Ointment around a chronic leg ulcer, as you may be at increased risk for a local allergic reaction or infection
- you are applying Dermovate Ointment near the eyes or on the eyelids, as cataracts or glaucoma may develop if the ointment repeatedly enters the eye
- you are applying Dermovate Ointment to thin skin such as the face, since Dermovate Ointment can cause skin thinning. Use of Dermovate Ointment on the face should be limited to 5 days. Dressings or bandages should not be used on the skin of the face where the ointment is applied.

If an infection develops while using the medicine, consult with the physician or pharmacist.

Contact your physician if you experience blurred vision or other visual disturbances.

If you are not sure if any of the above apply to you, talk to your physician or pharmacist before using this medicine.

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 you experience a recurrence of your condition shortly after stopping treatment, within 2 weeks, do not restart using the ointment/cream without consulting your physician unless your physician has previously advised you to do so. 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 on children under 1 year of age.
- Avoid prolonged use in children and infants over 1 year of age, as their skin is thinner than adults and as a result, may absorb a larger amount of the preparation.
- Use in children should be limited to 5 days and accompanied by a weekly check-up.
- In children, dressings or bandages should not be used in the area where the ointment is applied.

When coming in contact with fabrics, such as dressings, clothing or bedding, Dermovate Ointment may cause them to be easily ignited by a naked flame. Therefore, keep away from fire when using Dermovate Ointment.

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 use Dermovate Ointment while breast-feeding, do not apply the ointment on the breast area to prevent a situation in which the ointment accidentally gets into the mouth of the baby.

Important information about some of the ingredients in the medicine

Dermovate Ointment contains 50 mg propylene glycol per gram of product. Propylene glycol may cause skin irritation.

Whilst using Dermovate Ointment, 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.

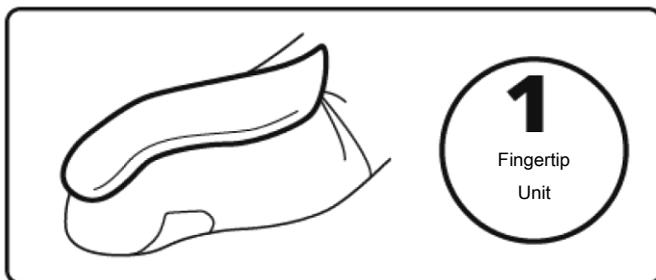
- The recommended dosage is usually application of a thin layer of Dermovate Ointment 1 or 2 times a day. The dosage may be reduced as your skin begins to get better, or stopped when it is better. Your physician may prescribe for you a weaker steroidal medicine instead.
- If you are also using a moisturizer, allow time for Dermovate Ointment to be absorbed into your skin before applying the moisturizer.
- This ointment is intended for use on your skin only.
- Do not use this ointment for more than 4 weeks without consulting your physician. If you need treatment for a long time, your physician may decide you need to use a milder cream or ointment.
- If your skin problem worsens or does not improve within 2 to 4 weeks, consult with 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 skin infection under the dressing.
- If you are applying the ointment on someone else, make sure you wash your hands after use or wear disposable gloves.

Do not exceed the recommended dose.

For external use only.

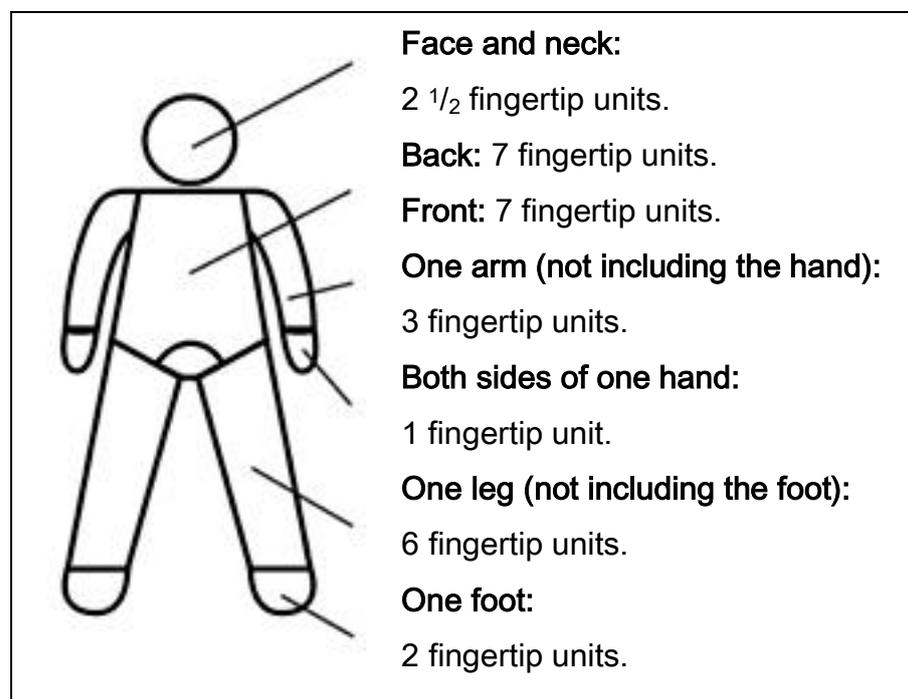
Instructions for applying the ointment

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 the amount of Dermovate Ointment to use with your fingertip (as demonstrated in the illustration below). For children, you will need to use less ointment, but still use an adult finger to measure out the fingertip unit.



3. Wash your hands again after using the ointment unless you intended to apply it to your hands as a part of the treatment.

Use in adults



Do not worry if you find you need a little more or less ointment than this. It is only a rough guide.

Use in children between 1 and 10 years of age

The number of required fingertip units:					
Child's age	Face and neck	Arm and hand	Leg and foot	Front	Back including buttocks
1-2 years	1 1/2	1 1/2	2	2	3
3-5 years	1 1/2	2	3	3	3 1/2
6-10 years	2	2 1/2	4 1/2	3 1/2	5

- Do not use this medicine on children under 1 year of age.
- It is especially important in children not to exceed the recommended dose.
- A course of treatment for a child should not last more than 5 days – unless your physician has told you to use the ointment for longer. The physician may want to see the child every week, whilst using the ointment.
- Do not use dressings and bandages on children in areas where the ointment is applied.

If you have psoriasis

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

If you apply Dermovate Ointment to your face

You should only apply the ointment to your face if your physician tells you to. Limit the use to 5 days only, as the facial skin thins easily. Do not use dressings or bandages on facial skin where the ointment is applied.

Do not allow the ointment to get into your eyes. If it happens, wash the ointment out with plenty of water.

If you accidentally have taken a higher dosage

If you applied too much or if you accidentally swallowed the ointment, you might become ill. Refer 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 proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine

If you forgot to apply your ointment, apply it as soon as you remember. If it is close to the time you are next meant to apply it, wait until that time.

Do not apply extra Dermovate Ointment 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 Ointment 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 use of the medicine, consult the physician or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Dermovate Ointment 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 Ointment 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 ointment, have an infection or need a different treatment.
- You have psoriasis and you develop raised bumps with pus under the skin. This may happen during or after the treatment and is known as pustular psoriasis.

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

Common side effects

These may affect up to 1 in 10 people:

- A feeling of burning, pain, irritation or itching at the ointment application site.

Uncommon side effects

These may affect up to 1 in 100 people:

- Thinning of the skin, stretch marks may develop
- 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 Ointment 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 amount of body hair
- Hair loss/lack of hair growth/damaged looking hair.

Additional very rare skin side effects that may occur:

- Allergic reaction at the site of application
- Worsening of the condition of the skin
- Irritation or pain at the application site
- Redness
- Rash or hives
- If you have psoriasis, you may develop raised bumps with pus under the skin. This can happen very rarely during or after the treatment and is known

as pustular psoriasis

- Skin infection
- Acne.

In children, also pay attention to the following signs:

- Delayed weight gain
- Delayed growth.

Very rare side effects that may show up in blood test results or during 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.
- After first opening, can be used for a duration of 3 months.
- 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:
White soft paraffin, propylene glycol (see section 2) and sorbitan sesquioleate
- 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 ointment.
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: 027-57-22063.

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