

Package leaflet: information for the user

Dermovate cream 0.5 mg/g

Dermovate ointment 0.5 mg/g

Dermovate cutaneous solution 0.5 mg/g

clobetasol-17-propionate

Read the entire leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Do you have any questions? Contact your doctor, pharmacist, or nurse.
- Do not pass this medicine on to others, as it has been prescribed only for you. It may harm them, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor, pharmacist, or nurse.

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1. What is Dermovate and what is it used for?

The active substance in Dermovate is clobetasol-17-propionate. This is a corticosteroid (adrenal cortex hormone) that helps reduce symptoms caused by skin conditions. Dermovate is quickly absorbed into the skin after application. This reduces symptoms such as itching, redness, swelling, and scaling. Dermovate addresses the symptoms but not the cause of the skin problems.

Your doctor has prescribed Dermovate cream or ointment to treat the symptoms of certain skin conditions you are experiencing. These are local/topical skin conditions that only respond well to very potent corticosteroids like Dermovate.

Examples of these skin conditions include:

- thickened patches of inflamed, red skin often covered by silvery scales (psoriasis)
- certain forms of eczema (lichenified eczema)
- skin disease that often affects the face, ears, and scalp and increases the sensitivity of the affected skin to sunlight (discoid lupus erythematosus)
- itchy and red small bumps of the skin (hypertrophic lichen)
- itchy and red swollen scars (scar hypertrophy)

Your doctor has prescribed Dermovate solution to reduce the redness and itching of certain scalp problems, such as psoriasis and dermatoses that do not respond to medication (recalcitrant dermatoses).

All formulations:

For adults, the elderly, and children from one year old, this medication can be used for skin inflammation (dermatitis) that does not respond to creams and ointments of less potent steroids.

2. When should you not use this medication or be extra careful with it?

When should you not use this medication?

- You are allergic to any of the substances in this medication. You can find these substances in section 6 of this leaflet.

For the treatment of the following skin problems because they may worsen:

- untreated skin infections (caused by viruses, bacteria, fungi, and/or parasites)
- with redness with or without pimples on the face (rosacea)
- red rash around the mouth (perioral dermatitis)
- itchy skin (pruritus) that is not inflamed
- for the treatment of itching of the anus or genitals (perianal and genital pruritus)
- in skin conditions with scaly flakes (ichthyosis), skin conditions that occur in youth (juvenile dermatosis), fragility of the skin vessels
- on skin conditions caused by the use of corticosteroids, such as stretch marks (striae atrophica)
- acne (acne vulgaris)

Children under 1 year

- do not use in skin diseases (dermatoses), including eczema due to congenital hypersensitivity (constitutional eczema)

All formulations

If you think any of the above situations apply to you, do not use this medicine, but first contact your doctor or pharmacist.

When should you be extra careful with this medicine?

- use this medicine as long as your doctor has prescribed it. If your condition does not improve after 2-4 weeks of treatment, contact your doctor.
- in systemic effects of this medicine such as suppression of adrenal cortex function, growth retardation in children, bone demineralization after prolonged use, weight gain, and moon face (Cushing's syndrome). If this is the case, you should not abruptly stop using this medicine but contact your treating physician.
- contact your doctor or pharmacist before using this medicine if you experience newly developed bone pain or worsening of existing bone complaints during treatment with Dermovate, especially if you have used Dermovate for a long time or repeatedly.
- contact your doctor or pharmacist before using this medicine if you are using other medicines that you take or apply to the skin and that contain corticosteroids or medicines intended to regulate your body's defense (immune system) (e.g., in an autoimmune disease or after a transplant). Combining Dermovate with these medicines can lead to serious infections.
- if there is a risk of an increase in systemic effects due to:
 - strength and composition (formulation) of the medicine applied to the skin
 - the duration of time the skin is in contact with the medicine
 - application on a large surface area

- use on occluded skin surfaces, such as under occlusive dressings and in cases of redness or pain in skin folds (e.g., between the thighs and in the armpits)
- use on areas where the skin is naturally thinner such as the face, body folds, or genitals
- use on areas where the skin is damaged or in other conditions where the skin may be damaged
- reduced kidney and liver function
- in children and the elderly
- with prolonged use of this medicine in a baby or young child, regular monitoring of height and weight is necessary. Use in young children is only allowed on the advice of a doctor.
- if this medicine is applied under an occlusive dressing. Use an occlusive dressing over this medicine only if your doctor has advised you to do so. The skin must be cleaned before applying a new dressing to prevent infections; this also applies to the use of this medicine under your child's diaper.
- if you have psoriasis. There is a possibility that over time you may respond less well to this medicine. This is called tolerance, and there is a risk that generalized pustular psoriasis may occur.
- with prolonged and intensive use of this medicine. This can cause local skin atrophy, such as thinning of the skin and stretch marks (striae), especially when occlusive dressings are used or when this medicine is used in skin folds. Prolonged application on the face is less desirable, as this skin is more sensitive to changes in skin thickness.
- when using this medicine on the eyelids. Do not use this medicine on the eyelids due to the risk of developing glaucoma or cataracts if this medicine gets into the eyes.
- with concurrent infections with microorganisms such as bacteria, parasites, fungi, and viruses. These infections can be hidden or worsened by improper use of this medicine. When the infection is treated, an appropriate antimicrobial medicine should be used. If the infection spreads, Dermovate should be discontinued and antimicrobial treatment should be started and/or continued.
- if you have eczema around a leg ulcer, a topically used corticosteroid can increase the risk of an allergic reaction or infection around the ulcer.
- in case of hypersensitivity reactions at the application site that may resemble the symptoms for which the treatment is applied. If this is the case, you should contact your treating physician.
- contact your doctor if you experience blurred vision or other visual disturbances.

Liquid:

- the treated scalp should not be wrapped or otherwise covered unless advised by your doctor. Wrapping or covering the skin makes it easier for the active substance to pass through the skin barrier and increases the risk of infection.

Contact your doctor or pharmacist before using this medicine.

Are you using any other medicines?

Are you using any other medicines besides Dermovate, have you done so recently, or are you planning to do so soon? If so, tell your doctor or pharmacist.

Some medicines can affect how this medicine works or increase the chance of side effects.

Medicines for which this applies include:

ritonavir (antiviral medicine) and itraconazole (antifungal medicine)

Pregnancy, breastfeeding and fertility

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine.

Driving and using machines

There is no data available on the effect of this medicine on driving ability. However, an effect is not expected.

Substances in this medicine you should be aware of

If you are sensitive to them, the following excipients may cause a problem (for a complete list of excipients see section 6 of this leaflet):

Dermovate cream contains:

- propylene glycol (E1520); this medicine contains 475 mg of propylene glycol per g of cream. Propylene glycol may cause skin irritation
- cetostearyl alcohol, may cause local skin reactions (e.g., eczema, contact dermatitis)
- chlorocresol (preservative), may cause allergic reactions

Dermovate ointment contains:

- propylene glycol (E1520); this medicine contains 50 mg of propylene glycol per g of ointment. Propylene glycol may cause skin irritation

Dermovate liquid contains:

- isopropyl alcohol, may cause eye irritation

3. How to use this medicine?

Always use this medicine exactly as your doctor or pharmacist has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

The recommended dosage is:

- use once or twice a day. The number of times you use this medicine can be reduced once your skin condition improves or if your doctor has prescribed a weaker corticosteroid instead.
- use this medicine for as long as your doctor has prescribed it. If your condition does not improve after 2-4 weeks of treatment, contact your doctor.
- when you have used this medicine for 4 consecutive weeks, your doctor should check the condition of your skin. No more than 30 - 60 grams of this medicine should be used per week, unless your doctor prescribes otherwise.

How should you use this medicine?

Cream and ointment:

- normally, a thin layer is applied to the affected skin. It is best to apply this medicine by gently and evenly rubbing it into the skin. If you want to shower, apply this medicine to the skin only afterwards.
- wash your hands after application to remove any residue of this medicine, unless your hands need to be treated.
- allow sufficient time for absorption after each application before using a skincare cream.

If your eczema frequently recurs, your doctor may suggest using this medicine in a less frequent dosage once your eczema is under control, to ensure it does not return.

For example: your doctor may advise applying a thin layer once a day twice a week on the eczema spots or on the areas where it is expected to recur.

Liquid:

If you have washed your hair or used a shampoo, your hair must be dry before using the liquid.

Because the liquid can ignite, you should not smoke or be near open flames when applying the liquid and shortly after using it. Do not dry your hair with a hairdryer immediately after applying the liquid. Also avoid contact with your eyes.

Remove the cap from the squeeze bottle and place the nozzle above the scalp to be treated. Gently squeeze the bottle to apply a thin, even layer. You can rub in the liquid, but this is not necessary. Until the liquid has dried, your scalp will feel cool.

Have you used too much of this medicine?

If you have applied too much of this medicine once, you do not need to worry. The occurrence of an acute overdose is very unlikely. If you have applied more or more frequently than your doctor has prescribed for a long time, or if you have ingested a large amount, you may become ill. If you have ingested a large amount of this medicine, rinse your mouth with large amounts of water and contact your doctor or pharmacist for advice. There is a risk of a high concentration of corticosteroids in your body (hypercorticism, see section 4 'Possible side effects').

In that case, the treatment should be gradually reduced or stopped under medical supervision due to the risk of adrenal suppression.

Have you forgotten to use this medicine?

Do not take a double dose to make up for a forgotten dose. Use the normal amount when you realize you have forgotten to apply this medicine once. If it is almost time for the next treatment, you can also wait to apply until the time of the next treatment.

If you stop using this medicine

If you use this medicine regularly, contact your doctor before stopping its use.

Do you have any other questions about using this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

Like any medicine, this medicine can also have side effects. Not everyone will experience them.

Side effects will be visible on your skin and may affect other parts of your body if a large amount of the medicine is absorbed through the skin and enters your bloodstream.

If your skin condition worsens, or if your skin becomes swollen during treatment, you may be allergic to the medicine, have an infection, or need a different treatment.

Then stop using this medicine and contact your doctor as soon as possible.

The following side effects have been reported with the use of this medicine:

Uncommon side effects

These may occur in up to 1 in 100 people

- thinning of the skin, which may lead to stretch marks (striae)

- the appearance of blood vessels under the skin surface (telangiectasia)

Frequency not known, but may occur:

Prolonged use of this medicine, or use under an occlusive dressing, may cause the following symptoms:

- weight gain/obesity

- moon face, large abdominal circumference (central obesity) (Cushing's syndrome)

- thinning of the skin

- aging of the skin

- dry skin

- pigment changes

- excessive hair growth (hypertrichosis)

- hair loss/lack of hair growth (alopecia)/hair that appears damaged (trichorrhexis)

- pimples

- blurred vision or other vision problems caused by detachment of the retina of the eye (central serous chorioretinopathy)

Other common skin reactions (frequency not known) that may occur include:

- itchy skin (pruritus)

- localized burning or painful sensation of the skin

- allergic reaction at the site where the medication is applied

- exacerbation of underlying symptoms

- redness of the skin (erythema)

- skin rash

- hives or welts (urticaria)

- psoriasis accompanied by pimples (pustular psoriasis)

- infection that may occur in people with reduced resistance (opportunistic infection)

- localized orange-yellow granules due to skin blockage in older patients (milia)

- bruising (purpura)

- eczema-like reddish rash on the face sometimes with pimples (rosacea) with or without thinning of the skin

Additional side effects that may occur in children (frequency not known):

- delayed weight gain

- slow growth

Side effects that may appear from blood tests or when your doctor examines you (frequency not known):

- decreased levels of naturally occurring adrenal cortex hormone (cortisol)

- high blood sugar levels (hyperglycemia)/glucose in the urine (glucosuria)

- increased blood pressure (hypertension)

- bone thinning (osteoporosis)

cataract
glaucoma

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this leaflet. You can also report side effects via the Netherlands Pharmacovigilance Centre Lareb. Website: www.lareb.nl. By reporting side effects, you help us obtain more information about the safety of this medicine.

5. How do you store this medicine?

Cream:

Store below 25°C. Do not freeze.

Ointment:

Store below 25°C.

Liquid:

Store below 25°C. Do not freeze.

Keep the container tightly closed when not in use. The contents are flammable. Keep away from all sources of fire, flames, and heat. Do not leave the liquid in direct sunlight.

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. You can find it on the box and the tube/bottle after EXP. It includes a month and a year. The last day of that month is the expiry date.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. Proper disposal of medicines ensures they are destroyed correctly and do not enter the environment.

6. Contents of the package and other information

What substances are in this medicine?

- The active substance in this medicine is clobetasol-17-propionate.
- The other substances in the cream are: chlorocresol (preservative), glyceryl monostearate (E471), Arlacel 165 (emulsifier), cetostearyl alcohol, white beeswax substitute 6621, propylene glycol (E1520), sodium citrate (E331), citric acid monohydrate (E330), and purified water.
- The other substances in the ointment are: propylene glycol (E1520), sorbitan sesquioleate, and petroleum jelly.
- The other substances in the liquid are: carbomer, isopropyl alcohol, sodium hydroxide (E524), and purified water.

What does Dermovate look like and what is in a package?

Dermovate cream is supplied in tubes of 15 grams, 30 grams, or 100 grams. The contents of the tube consist of a white, smooth cream.

Dermovate ointment is supplied in tubes of 15 grams, 30 grams, or 100 grams. The contents of the tube consist of a grey, smooth translucent ointment.

Dermovate liquid is supplied in a bottle with a content of 30 grams or 100 grams. The contents of this bottle consist of a colorless transparent, slightly viscous liquid with a strong, somewhat sweet (isopropyl alcohol) odor.

It is possible that not all mentioned package sizes are marketed.

Marketing authorization holder and manufacturer

Marketing authorization holder

GlaxoSmithKline BV
Van Asch van Wijckstraat 55H
3811 LP Amersfoort
033 2081100

Dermovate cream 0.5 mg/g	RVG 06932
Dermovate ointment 0.5 mg/g	RVG 06933
Dermovate liquid for cutaneous use	RVG 07579

Manufacturer

Cream and ointment:
Delpharm Poznań Spółka Akcyjna ul. Grunwaldzka 189 60-322 Poznan
Poland

Liquid:
Aspen Bad Oldesloe GmbH
Industriestrasse 32-36
D-23843, Bad Oldesloe
Germany

This leaflet was last approved in June 2022.

More information about this medicine can be found on the website of the Medicines Evaluation Board: www.cbg-meb.nl.