**Dermovate cream 0.5 mg/g**

**What is Dermovate and what is it used for?**The active ingredient in Dermovate is clobetasol-17-propionate. This is a corticosteroid (adrenal cortex hormone) that reduces the symptoms caused by skin disorders. Dermovate quickly penetrates the skin after application, reducing symptoms such as itching, redness, swelling, and scaling. Dermovate addresses the consequences, not the cause, of skin problems.

Your doctor has prescribed Dermovate cream or ointment to treat the symptoms of certain skin conditions that you are experiencing. These are local 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 with silvery scales (psoriasis)
* Certain forms of eczema (lichenified eczema)
* Skin disease that often affects the face, ears, and hairy scalp and increases the sensitivity of the affected skin to sunlight (discoid lupus erythematosus)
* Itchy and red small skin bumps (hypertrophic lichen)
* Itchy and red swollen scars (hypertrophic scars)
* Your doctor has prescribed Dermovate solution to reduce the redness and itching associated with certain scalp problems, such as psoriasis and non-medication-responsive dermatoses (recalcitrant dermatoses).

**All formulations:** For adults, the elderly, and children aged one year and older, this medicine can be used for skin inflammation (dermatitis) that does not respond to creams and ointments with less potent steroids.

**When should you not use this medicine or take extra precautions?
When should you not use this medicine?**

If you are allergic to any of the ingredients in this medicine.

For the treatment of the following skin problems, as they may worsen:

* Untreated skin infections (caused by viruses, bacteria, fungi, and/or parasites)
* Redness with or without pimples on the face (rosacea)
* Red rash around the mouth (perioral dermatitis)
* Itchy skin (pruritus) without inflammation
* Treatment of itching in the anus or genital area (perianal and genital pruritus)
* Skin conditions with scaly flakes (ichthyosis), skin conditions occurring in youth (juvenile dermatosis), fragility of the skin vessels
* Skin conditions caused by the use of corticosteroids, such as stretch marks (striae atrophica)
* Teenage acne (acne vulgaris)
* Children under 1 year of age
* Do not use for skin diseases (dermatoses), including eczema due to congenital hypersensitivity (atopic eczema)

**All formulations**If you think any of the above situations apply to you, do not use this medicine and first consult your doctor or pharmacist.

**When should you take extra precautions with this medicine?**

* Use this medicine for the duration prescribed by your doctor. If your condition does not improve after 2-4 weeks of treatment, contact your doctor.
* Be cautious of systemic effects of this medicine, such as adrenal suppression, growth retardation in children, bone loss with prolonged use, weight gain, and moon face (Cushing's syndrome). If this occurs, do not abruptly discontinue the use of this medicine; instead, contact your treating doctor.
* Contact your doctor or pharmacist before using this medicine if you experience newly developed bone pain or worsening of existing bone conditions during treatment with Dermovate, especially if you have used Dermovate for a prolonged or repeated period.
* Contact your doctor or pharmacist before using this medicine if you are taking or applying other medications that contain corticosteroids or medications intended to regulate your body's immune system (e.g., for autoimmune diseases or after transplantation). Combining Dermovate with these medications can lead to severe infections.
* If there is a risk of increased systemic effects due to:
* Strength and composition (formulation) of the topical medication
* Duration of skin contact with the medication
* Application on a large surface area
* Use on occluded skin surfaces, such as under occlusive dressings and in skin folds with redness or pain (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 genitalia
* Use on areas where the skin is damaged or in other conditions where the skin may be compromised
* Impaired kidney and liver function
* In children and the elderly
* Long-term use of this medicine in a baby or young child requires regular monitoring of their height and weight. Use in young children is only allowed under the advice of a doctor.
* If this medicine is applied under an occlusive dressing. Use an occlusive dressing over this medicine only if advised by your doctor. The skin should bebe 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 become less responsive to this medicine. This is called tolerance, and there is a risk that generalized pustular psoriasis may occur throughout the body.
* With prolonged and intensive use of this medicine, local skin atrophy may occur, such as thinning of the skin and skin striae (stretch marks), especially when occlusive dressings are used or when this medicine is used in skin folds. Prolonged application on the face is less desirable as the 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 green cataracts (glaucoma) or gray cataracts (cataract) if the medicine comes into contact with the eyes.
* In the presence of concurrent infections with microorganisms such as bacteria, parasites, fungi, and viruses. These infections can be concealed or exacerbated by incorrect use of this medicine. When treating the infection, an appropriate antimicrobial medicine for these microorganisms should be used. If the infection spreads, Dermovate should be discontinued, and antimicrobial treatment should be initiated and/or continued.
* If you have eczema around a leg ulcer, topical corticosteroid use may increase the risk of an allergic reaction or infection around the ulcer.
* In case of hypersensitivity reactions at the site of administration that may resemble the symptoms being treated. If this occurs, contact your treating doctor.
* Contact your doctor if you experience blurred vision or other visual disturbances.

**Solution:** The treated scalp should not be wrapped or covered in any other way unless advised by your doctor. Wrapping or covering the skin makes it easier for the active ingredient to penetrate the skin barrier and increases the risk of infection. Contact your doctor or pharmacist before using this medicine.

**Are you taking any other medicines?**If you are taking or have recently taken any other medicines, including non-prescription medicines and herbal remedies, tell your doctor or pharmacist.

Some medicines may affect how this medicine works or may increase the likelihood of experiencing side effects. Medicines that may interact include: Ritonavir (antiviral medicine) and itraconazole (antifungal medicine).

**Pregnancy, breastfeeding, and fertility:** If you are pregnant, think you may be pregnant, planning to become pregnant, or breastfeeding, contact your doctor or pharmacist before using this medicine.

**Driving and using machines:**

There is no known effect of this medicine on driving ability. However, no effect is expected.

**Ingredients in this medicine to consider:** If you are sensitive to them, the following excipients may cause problems (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 gram of cream. Propylene glycol can cause skin irritation.

* cetostearyl alcohol can cause local skin reactions (e.g., eczema, contact dermatitis).
* chlorocresol (preservative) can cause allergic reactions.

**How to use this medicine?**Always use this medicine exactly as your doctor or pharmacist has told you. If you are unsure about the correct usage, contact your doctor or pharmacist.

**The recommended dosage is:** Use once or twice a day. The frequency of use may be reduced once your skin condition improves or if your doctor has prescribed a weaker corticosteroid instead.

Use this medicine for the duration prescribed by your doctor. If your condition does not improve after 2-4 weeks of treatment, contact your doctor.

If you have used this medicine for 4 weeks continuously, your doctor should assess the condition of your skin. No more than 30-60 grams of this medicine should be used per week, unless otherwise prescribed by your doctor.

**How to use this medicine:**

* Cream and ointment:
* Normally, apply a thin layer 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 after showering.
* Wash your hands after applying the medicine to remove any residue, unless your hands need to be treated.
* Allow sufficient time for the medicine to absorb before using any moisturizing cream.
* If your eczema recurs regularly, your doctor may suggest using this medicine in a less frequent dosage once your eczema is under control to prevent its recurrence.
* For example, your doctor may advise applying a thin layer twice a week, once daily, to the eczema spots or the areas where it is expected to reoccur.

**Have you used too much of this medicine?**If you have applied too much of this medicine once, there is no need to worry. The occurrence of acute overdose is highly unlikely. However, if you have applied more or more frequently than prescribed by your doctor over a prolonged period of time, or if you have ingested a large amount, it may make you feel unwell. If you have ingested a large amount of this medicine, rinse your mouth with large amounts of water and seek advice from your doctor or pharmacist. There is a possibility of excessive concentration of corticosteroids in your body (hypercorticism, see section 4 'Possible side effects').

In such cases, treatment should be gradually reduced or discontinued under medical supervision due to the risk of adrenal suppression.

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

**If you stop using this medicine**If you use this medicine regularly, contact your doctor before discontinuing its use. Do you have any other questions about the use of this medicine? Contact your doctor or pharmacist.

**Possible side effects**Like any medicine, this medicine can have side effects. Not everyone experiences them. Side effects may 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 require alternative treatment. In that case, 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:**

**Common side effects**

**These may occur in up to 1 in 100 people:**

* Thinning of the skin, which may lead to stretch marks (striae)
* Visible blood vessels under the skin surface (telangiectasia)
* Frequency not known, but may occur:
* Prolonged use of this medicine or use under occlusive dressings may cause the following symptoms:
* Weight gain/obesity
* Moon face, large abdomen (central obesity) (Cushing's syndrome)
* Thinning of the skin
* Aging of the skin
* Dry skin
* Pigmentation changes
* Excessive hair growth (hypertrichosis)
* Hair loss/lack of hair growth (alopecia)/hair that appears damaged (trichorrhexis)
* Acne
* Blurred vision or other vision problems caused by detachment of the retina (central serous chorioretinopathy)

**Other common skin reactions (frequency unknown) that may occur include:**

* Itching of the skin (pruritus)
* Local burning or painful sensation of the skin
* Allergic reaction at the site of application
* Exacerbation of underlying symptoms
* Redness of the skin (erythema)
* Skin rash
* Hives or urticaria
* Pustular psoriasis
* Opportunistic infections in individuals with reduced immunity
* Localized orange-yellow granules due to skin blockage in elderly patients (milia)
* Bruising (purpura)
* Eczema-like red rash on the face, sometimes with pimples (rosacea), with or without thinning of the skin
* Additional side effects that may occur in children (frequency unknown):
* Delayed weight gain
* Slow growth

**Side effects that may be revealed through blood tests or medical examinations (frequency unknown):**

* Decreased levels of endogenous corticosteroids (cortisol)
* High blood sugar levels (hyperglycemia)/glucose in the urine (glucosuria)
* Increased blood pressure (hypertension)
* Osteoporosis
* Cataracts
* Glaucoma

**How to store this medicine**

* Cream: Store below 25°C. Do not freeze.
* Ointment: Store below 25°C.
* Keep the packaging 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.