

DERMOVATE CREAM / OINTMENT

Clobetasol propionate (0.05% w/w)

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What Dermovate is used for

Dermovate Cream and Ointment relieves the symptoms of certain skin problems

- frequently relapsing eczemas
- psoriasis (thickened patches of inflamed, red skin, often covered by silvery scales)
- lichen planus (a skin disease that causes itchy, reddish-purple, flat-topped bumps on the wrists, forearms or lower legs)
- discoid lupus erythematosus (a disease of the skin most often affecting the face, ears and scalp causing scarring and increased sensitivity of the affected skin to sunlight)
- conditions which do not respond satisfactorily to less potent steroids.

For children over the age of one year Dermovate Cream and Ointment is used for dermatitis that has not responded to milder steroid creams or ointments.

How Dermovate works

The name of your medicine is Dermovate Cream and Ointment. Dermovate Cream and Ointment contains clobetasol propionate which belongs to a group of medicines called steroids. Steroids help to reduce redness, swelling and irritation of the skin.

Before you use Dermovate

- When you must not use it

Don't use Dermovate Cream and Ointment to treat any of the following skin problems, it could make them worse:

- infected skin (unless the infection is being treated with an anti-infective medicine at the same time)
- acne
- rosacea (a facial skin condition where the nose, cheeks, chin, forehead or entire face are unusually red, with or without tiny visible blood vessels, bumps (papules) or pus-filled bumps (pustules))
- rashes around the mouth
- itchy skin which is not inflamed
- around the anus or genitals (penis and vagina)
- Don't use Dermovate on a child under 1 year

If you think any of these apply to you, don't use Dermovate Cream and Ointment until you have checked with your doctor or pharmacist.

- Before you start to use it

If you are pregnant, or think you could be, or if you are planning to become pregnant, don't use Dermovate Cream and Ointment without talking to your doctor first.

If you are breast-feeding, you must check with your doctor before you use Dermovate Cream and Ointment.

- If you do use Dermovate when breast-feeding, don't use Dermovate on your breast area to ensure that the baby does not accidentally get Dermovate in their mouth.

- Taking other medicines

Some medicines may affect how Dermovate Cream and Ointment works or make it more likely that you'll have side effects. Examples of these medicines include:

- Ritonavir and itraconazole. Tell your doctor or pharmacist if you are taking any of these. There are other medicines which may have a similar effect. It's therefore very important to tell your doctor or pharmacist if you're taking any other medicines, if you've taken any recently, or if you start taking a new one. This includes medicines bought without a prescription.

How to use Dermovate

- How much to use

Always use Dermovate Cream and Ointment exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Use Dermovate Cream or Ointment once or twice daily. The number of times you use your medicine may be reduced as your skin gets better or your doctor may prescribe a weaker steroid for you to use instead.

- Apply a thin layer and gently rub in, using only enough to cover the entire affected area.
- Wash your hands after use unless treating the hands.
- If you are also using an emollient (moisturising) preparation allow time for Dermovate to be absorbed after each application before applying the emollient.
- This medicine should not be used every day for more than four weeks at a time.

If your eczema flares up frequently, your doctor may suggest that you use a less frequent dose of Dermovate once your eczema is under control, to help stop your eczema from coming back.

For example, you may be advised to apply a thin film of Dermovate once daily, two times a week to areas of skin which have been affected by eczema, or to those areas where it is likely to re-appear.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Don't stop using Dermovate Cream and Ointment without advice. If you use Dermovate regularly make sure you talk to your doctor before you stop using it.

- If you forget to use it

If you forget to use Dermovate Cream and Ointment apply it as soon as you remember then continue as before.

Do not apply extra Dermovate to make up for missed doses.

- If you use too much (overdose)

If you apply a large amount of Dermovate Cream and Ointment or accidentally swallow a lot of Dermovate, it could make you ill. If you do swallow a large amount of Dermovate, rinse your mouth out with plenty of water and contact your doctor or pharmacist for advice.

While you are using it

- Things you must do

Check with your doctor or pharmacist before taking your medicine and take it as prescribed by your doctor.

- Things you must not do

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

- Things to be careful of

- Tell your doctor if you are allergic (hypersensitive) to Dermovate Cream and Ointment or any of the ingredients
- Only use Dermovate for as long as your doctor recommends. If your condition does not improve within 2-4 weeks of treatment, speak to your doctor.
- Take care when applying Dermovate to the eyelids to make sure it does not get into your eye.
- Take care when applying Dermovate to the face over a long period of time as it may cause skin thinning.
- If you have eczema around a leg ulcer, use of a topical corticosteroid may increase the risk of an allergic reaction or an infection around the ulcer.
- Only use an airtight dressing over this medicine if your doctor has told you to. If you are applying Dermovate under an airtight dressing, including a child's nappy, make sure that the skin is cleansed before a fresh dressing is applied to prevent infections.
- Whilst using Dermovate Cream and 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.

Contact your doctor if an infection develops. (See Side Effects).

If you experience blurred vision or other visual disturbances, speak to your doctor.

Side Effects

Like all medicines Dermovate Cream or Ointment can have side effects although not everybody gets them.

Side effects will affect your skin and may affect other parts of your body if a sufficient quantity of medicine is absorbed through the skin and enters your blood stream.

If your skin condition gets worse or your skin becomes swollen during treatment, you may be allergic to the medicine, have an infection or need other treatment. Stop using Dermovate Cream or Ointment and tell your doctor as soon as possible.

Common side effects

These may affect up to 1 in 10 people

- itchy skin
- local skin burning or pain

Uncommon side effects

These may affect up to 1 in 100 people

- skin thinning, this may cause stretch marks
- the appearance of blood vessels under the surface of your skin

Very rare side effects

These may affect up to 1 in 10,000 people

Use of Dermovate Cream or Ointment for a long period of time, or use under an airtight

dressing, may cause the following symptoms:

- increased weight
- moon face / rounding of the face
- obesity
- skin thinning
- skin wrinkling
- skin dryness
- changes to the colour of your skin
- increased body hair
- hair loss / lack of hair growth/damaged looking hair

Other very rare skin reactions that may occur are:

- allergic reaction at the site of application
- worsening of condition
- application site irritation
- redness
- rash or hives
- if you have psoriasis you may get raised bumps with pus under the skin. This can happen very rarely during or after treatment and is known as pustular psoriasis.
- skin infection
- acne

In children also look out for the following symptoms:

- delayed weight gain
- slow growth

Very rare side effects that may show up in blood tests or when your doctor gives you a medical examination:

- a decrease in the level of the hormone cortisol in your blood
- increased levels of sugar in your blood or urine
- high blood pressure
- cloudy lens in the eye (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 mineral (osteoporosis); additional tests may be needed after your medical examination to confirm if you have this condition.

If you get side effects
Tell your doctor or pharmacist if any of the side effects listed becomes severe or troublesome, or if you notice any side effects not listed in this leaflet.

You may report any side effects of adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my (Consumers → Reporting Side Effects to Medicine (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of Dermovate

- Storage

Keep this medicine out of the sight and reach of children.

Don't use Dermovate Cream or Ointment after the expiry date on the tube or carton (Exp).

Cream:
Store below 30°C.

Ointment:
Store below 30°C.

- Disposal

Don't dispose of medicines in wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. This will help protect the environment.

Product Description

- What it looks like

Dermovate Cream is a smooth white to off-white cream containing 0.05% w/w Clobetasol 17-propionate in a water miscible cream base. Dermovate Cream also contains Chlorocresol 0.075% w/w as preservative.

Dermovate Ointment is a smooth white to off-white translucent ointment containing 0.05% w/w Clobetasol 17-propionate in a paraffin base.

Dermovate Cream and Ointment are packed in collapsible aluminium tubes.

- Ingredients

- Active ingredient(s)

Clobetasol propionate

- Inactive ingredient(s)

Cream:

Glycerol monostearate, Cetostearyl alcohol, Chlorocresol, Sodium citrate, Citric acid (monohydrate), Purified water, Arlacel 165, Beeswax substitute 6621, Propylene glycol.

Ointment:

Propylene glycol, White soft paraffin, Sorbitan sesquioleate.

For important information about some of these ingredients see section '**While you are using it**'.

- MAL number

Dermovate Cream 0.05%
- MAL19961265ACRZ

Dermovate Ointment 0.05%
- MAL19961267ACRZ

Manufacturer

Delpharm Poznań Spółka Akcyjna
ul. Grunwaldzka 189
60-322 Poznań,
Poland.

Product Registration Holder

GlaxoSmithKline Pharmaceutical
Sdn. Bhd.
HZ.01, Horizon Penthouse,
1 Powerhouse,
1, Persiaran Bandar
Utama, Bandar Utama,
47800 Petaling Jaya
Selangor, Malaysia

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