

DERMOVATE CREAM / OINTMENT

Clobetasol propionate (0.05% w/w)

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What Dermovate is used for

Your doctor has chosen this Cream or Ointment to suit you and your condition. Dermovate Cream and Ointment are used for the short term treatment of inflamed skin conditions, including difficult to treat eczemas, psoriasis, lichen planus and discoid lupus erythematosus which do not respond satisfactorily to less active steroids.

How Dermovate works

Dermovate Cream and Ointment are a group of medicines called topical steroids. "Topical" means they are put on the skin. Topical steroids reduce the redness and itchiness of certain skin problems.

Before you use Dermovate

- When you must not use it

You should not:

- Use on the face where the skin thins easily unless your doctor has advised you to.
- Let the Cream or Ointment get into your eyes as glaucoma (increased pressure in the eyes) might result.
- Use around the anus (back passage) or genitals (private

parts) unless directed by your doctor.

- Use on a child under one year of age.

- Use Dermovate Cream or Ointment for long periods of time. If you do not experience any improvement after 4 weeks of treatment, discuss this with your doctor.

- Use Dermovate if you have viral skin infections like herpes simplex and chicken pox. Consult your doctor if you have the above skin conditions.

- Use Dermovate if your skin has been infected with bacteria or fungi. Consult your doctor if you have skin infection before using Dermovate.

- Before you start to use it

If you answer "yes" to any of the following questions, tell your doctor about this before using your Cream or Ointment.

- Do you have acne or a condition called rosacea (severe flushing of the skin on and around the nose), or perioral dermatitis (spotty red rash around the mouth)?

- Have you been told you are allergic to Dermovate Cream or Ointment, clobetasol propionate or any of the other ingredients listed?

- If you have a skin condition called Psoriasis, careful supervision is needed. You are encouraged to inform your doctor if you have this condition, before using Dermovate.

- Skin should be cleansed before fresh dressing is applied. This is to prevent bacterial infections since moist and warm skin conditions may cause bacterial build up.

- Are you are breast-feeding?

- Do you think you may be pregnant, or are planning to become pregnant?

- Does the affected area have to be covered by a bandage or a child's nappy?

- Taking other medicines

Make sure that your doctor knows what other medicines you are taking, including those that you have bought yourself.

How to use Dermovate

- How much to use

Apply Dermovate Cream or Ointment sparingly to the affected skin areas once or twice daily.

You should wash your hands after applying clobetasol propionate, unless it is the hands that are being treated.

Unless told by your doctor: You should not use more than this.

You should not use on large areas of the body for a long time.

The Cream and Ointment are for use on the skin only.

Use your Cream or Ointment as your doctor has told you. The label on it will usually tell you how much to use and how often. If you are not sure, ask your doctor or pharmacist.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

If you use Dermovate regularly make sure you talk to your doctor before you stop using it. Only use Dermovate for as long as your doctor recommends.

- If you forget to use it

If you forget to apply your Cream or Ointment apply the usual amount when you remember or if it is close to your next application then wait until this time.

- If you use too much (overdose)

It is important to follow the instructions on this leaflet. If, on a few occasions by mistake you apply more than the recommended amount do not worry.

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

Absorption can be increased if Dermovate Cream or Ointment is used under bandages or a child's nappy. Use special care to apply the correct amount to children as children can absorb more medication through their

skin. If you have concerns or worries discuss them with your doctor.

Side Effects

When used in the right amount for the correct period of time most people find using this medication causes no problems.

As with all medicines a few people may find it causes side effects.

If you experience swelling of the eyelids, face or lips, stop using the medication immediately and consult your doctor, as this may be an allergic reaction.

Dermovate preparations may be absorbed through your skin into your bloodstream. This is not a problem if you use the right amount of medication and for the correct period of time. If you use too much medication or use it for a long time you may have changes in your skin where medication is applied, including thinning, the appearance of blood vessels, and changes in the colour or the amount of hair.

Local allergic reactions such as redness of the skin, rash, itching, hives (itchy rash) and local skin burning may occur at the site of application and may be similar to the symptoms of the skin disease being treated. If symptoms persist stop using the medication immediately and consult your doctor.

If large amounts Dermovate medication are used for very long periods, signs of adrenal suppression may be seen, which include slowing down of children's growth, unexplained weight gain and the appearance of acne.

If you have any symptoms you do not understand discuss them with your doctor or pharmacist.

You may report any side effects of adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting)

Storage and Disposal of Dermovate

- Storage

Store below 30°C. Do not use the medication after the expiry date shown as "Exp" on the tube end, carton and label.

Keep your Cream and Ointment where children cannot see or reach it. It may harm them.

- 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 translucent ointment containing 0.05% w/w Clobetasol 17-propionate in a paraffin base.

Dermovate Cream and Ointment are packed in collapsible aluminium tubes, with a polypropylene cap. Available in tubes of 15g and 100g.

- Ingredients

- Active ingredient(s)

0.5mg of clobetasol propionate in each 1g.

- 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.

- MAL number

Dermovate Cream 0.05%
- MAL19961265AZ

Dermovate Ointment 0.05%
- MAL19961267AZ

Manufacturer

Glaxo Wellcome Operations
Harmire Road, Barnard Castle
Durham DL12 8DT,
United Kingdom

Product Registration Holder

GlaxoSmithKline
Pharmaceutical Sdn. Bhd.
Level 6, Quill 9,
112 Jalan Semangat,
46300 Petaling Jaya,
Selangor, Malaysia

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