

DERMOL®

Clobetasol propionate 0.05% w/w Cream and Ointment



What is in this leaflet

Please read this leaflet carefully before you start using DERMOL CREAM or OINTMENT.

This leaflet answers some common questions about DERMOL CREAM and OINTMENT.

It does not contain all the information available on this medicine. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of using DERMOL CREAM or OINTMENT against the benefits expected it would have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What DERMOL CREAM or OINTMENT is used for

Your DERMOL CREAM or OINTMENT contains the active ingredient clobetasol propionate. It belongs to a group of medicines known as topical steroids. "Topical" means that they are applied onto the skin. Topical steroids are used to help reduce the inflammation that causes the redness and itchiness in a variety of conditions (they are not "anabolic" steroids which are sometimes misused by athletes).

DERMOL CREAM or OINTMENT is useful in treating various inflamed conditions of the skin such as:

- psoriasis
- severe forms of eczema
- lichen planus (chronic itchy skin of unknown origin)
- discoid lupus erythematosus (recurring scaly rash)

when milder topical steroids cannot treat the skin condition effectively.

DERMOL CREAM is used to treat skin condition on moist surfaces; DERMOL OINTMENT is useful for dry, scaly skin.

Your doctor may, however, prescribe DERMOL CREAM or OINTMENT for another reason. Ask your doctor if you have any questions about why DERMOL CREAM or OINTMENT has been prescribed for you.

DERMOL CREAM or OINTMENT is available on prescription from your doctor.

Before you use DERMOL CREAM or OINTMENT

When you must not apply it

Do not use DERMOL CREAM or OINTMENT if you are allergic to:

- clobetasol propionate or
- any other ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include unusual reddening of the face, skin rash or hives, itching on the skin, shortness of breath, wheezing or finding it difficult to breathe, swelling of the face, lips, tongue or other parts of the body.

Do not use DERMOL CREAM or OINTMENT as treatment for the following skin conditions.

- untreated infected skin
- rosacea (unusual reddening of the nose and cheeks)
- acne
- skin conditions involving the mouth area
- skin conditions around the anal or genital areas including genital herpes
- itchy skin which is not inflamed.

If your doctor advises the use of DERMOL CREAM or OINTMENT to treat one of the above skin complications, it is important you follow the doctor's instructions carefully.

DERMOL CREAM or OINTMENT should not be used on children under one year of age. Safety and effectiveness in children younger than 1 year have not been established.

Do not let the cream or ointment enter your eyes.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start using this medicine, talk to your doctor.

Before you apply it

Tell your doctor if:

- You have had an allergic reaction to any medicine, including DERMOL CREAM or OINTMENT or other previous treatments for your skin condition.
- You are pregnant or plan to become pregnant.

- You are breastfeeding or plan to breastfeed.
- You are applying within skin folds or under a dressing.
- You have any other skin problems or conditions, such as psoriasis.
- You have broken or infected skin.
- You are using the product for a chronic leg ulcer.
- You are applying to the face, especially around the eyes or on the eyelids.
- You are a current smoker.
- You use other oral/topical medication containing corticosteroids or medication intended to control your immune system (e.g. for autoimmune disease or after a transplantation). Combining DERMOL CREAM or OINTMENT with these medicines may result in serious infections.
- You experience newly developed bone pain or worsening of previous bone symptoms during a treatment with DERMOL CREAM or OINTMENT especially if you have been using DERMOL CREAM or OINTMENT for a prolonged time or repeatedly.

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

If you have not told your doctor about any of the above, tell them before you start using DERMOL CREAM or OINTMENT.

Taking other medicines

If you are taking any other medicines, including any you get without a prescription from a pharmacy, supermarket or health food shop, tell your doctor or pharmacist.

Some medicines and DERMOL CREAM or OINTMENT may interfere with each other. These include:

- ritonavir, a medicine to manage HIV.

- itraconazole, an anti-fungal agent.
- other oral or topical corticosteroids or medications intended to control your immune system (e.g. for autoimmune disease or after a transplantation).

These medicines may be affected by DERMOL CREAM or OINTMENT, or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while using DERMOL CREAM or OINTMENT

How to use your DERMOL CREAM or OINTMENT

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the container, ask your doctor or pharmacist for help.

DERMOL CREAM or OINTMENT should not be used in children under 1 year.

How much to use

Your doctor will tell you how much DERMOL CREAM or OINTMENT you need to apply each day. It is important that you only apply the DERMOL CREAM or OINTMENT as directed by your doctor.

Do not use more than the recommended amount. Applying more than this may allow the active ingredient in this medication to pass through the skin and into the blood stream. This could affect other parts of the body and may result in unwanted side effects.

Sometimes repeated short courses of DERMOL CREAM or OINTMENT

may be used to control your skin condition. **Your doctor may tell you to use a different amount. If so, follow their instructions carefully.**

When to use it

For adults, elderly and children over 1 year, apply thinly once or twice daily, as directed by your doctor.

Use your medicine at about the same time each day.

Using it at the same time each day will have the best effect. It will also help you remember when to use it.

How long to use it

Your doctor will advise you how long to use the DERMOL CREAM or OINTMENT.

Duration of treatment might take from a few days to a longer period of time. If you are using DERMOL to treat a skin condition on the face, do not use for longer than five days.

Children should not use DERMOL CREAM or OINTMENT for longer than five days.

Stop using DERMOL CREAM or OINTMENT once the skin condition has cleared.

Talk to your doctor if the skin condition has not improved or worsens within two to four weeks.

It is not recommended to use on large areas of the body for a long time. Less potent topical steroids should be used for conditions requiring treatment longer than four weeks.

If you forget to use it

If you forget to apply it, just apply it as soon as you remember and then use it again at the normal time. **Do not** apply twice as much to make up for a missed dose.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

While you are using DERMOL CREAM or OINTMENT

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are using DERMOL CREAM or OINTMENT.

Tell your doctor or pharmacist that you are using DERMOL CREAM or OINTMENT before you start any new medicine.

Tell your doctor if you develop a skin rash or hives, or you become pregnant while using DERMOL CREAM or OINTMENT.

If you are going to have surgery, tell the surgeon or anaesthetist that you are using DERMOL CREAM or OINTMENT. It may affect other medicines used during surgery.

If you are going to have any blood tests, tell your doctor that you are using DERMOL CREAM or OINTMENT. It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked, especially if your doctor has prescribed DERMOL CREAM or OINTMENT for psoriasis.

Avoid smoking whilst applying to the skin. Avoid fire, flame and heat after application.

If you are using DERMOL CREAM or OINTMENT under dressings, cleanse the skin before a fresh dressing is applied.

Wash your hands after applying DERMOL CREAM or OINTMENT **unless** it is the hands that are being treated.

If you use DERMOL CREAM or OINTMENT on the eyelids, be careful to avoid contact with the eyes. If the product does accidentally enter your eyes, rinse your eye(s) thoroughly with water.

Things you must not do

Do not use DERMOL CREAM or OINTMENT to treat any other complaints unless your doctor tells you to.

Do NOT give this medicine to anyone else, even if his or her symptoms seem similar to yours or they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how DERMOL CREAM or OINTMENT affects you. Children should be careful when riding bicycles or climbing trees.

In case of overdose

You should only apply the amount that has been prescribed by your doctor.

If you use too much (overdose)

Immediately contact your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) or go to the Emergency department at your nearest hospital, if you think that you may have applied too much, or if anyone else has applied or consumed any DERMOL CREAM or OINTMENT by mistake. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Take the container of DERMOL CREAM or OINTMENT with you if you can.

Keep telephone numbers for these places handy.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using DERMOL CREAM or OINTMENT. This medicine helps most people

with skin problems such as psoriasis or eczema but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Most people find that if they use the cream or ointment correctly, they will not experience any side effects. Applying DERMOL CREAM or OINTMENT over long periods of time, or using more than the recommended dose, may increase the chance of developing side effects.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- dry skin or skin wrinkling
- changes in hair growth and changes in the colour of your skin
- blood vessels that are close to the skin surface, becoming more visible
- your skin condition becomes pimply
- acne.

Tell your doctor as soon as possible if you notice any of the following effects:

- rash, inflammation or redness of the skin
- burning, pain, irritation or itching of the skin
- thinning of the skin and stretch marks
- weight gain, rounding of the face and high blood pressure
- cloudy vision or increased pressure in the eye
- blurred vision
- difficulty seeing (in either one or both eyes)
- increased severity in other untreated skin infections
- passing large amounts of urine, excessive thirst and having a dry mouth and

skin.

- After long term continuous use rebound flares can occur after stopping treatment (topical steroid withdrawal syndrome). A severe form of rebound flare can develop which takes the form of a dermatitis with intense redness, stinging, burning, itch, skin peeling, oozing pustules that can spread beyond the initial treatment area. It is more likely to occur when delicate skin sites such as the face and flexures are treated. Should there be a reoccurrence of the condition within days to weeks after successful treatment a withdrawal reaction should be suspected. Reapplication should be with caution and specialist advise is recommended in these cases or other treatment options should be discussed with your doctor.

The above list includes more serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Applying DERMOL over long periods of time, or using more than the recommended dose, or applying it under an airtight dressing or a nappy may increase the chance of developing side effects.

If your skin condition gets worse during treatment, stop applying DERMOL CREAM or OINTMENT and tell your pharmacist or doctor as soon as possible.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell. Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using DERMOL CREAM or OINTMENT

Storage

Keep your DERMOL CREAM or OINTMENT in the container until it is time to use it.

Store below 25°C and out of reach of children. Avoid exposure to heat, light and moisture. Do not leave product in direct sunlight.

Do not store the DERMOL CREAM or OINTMENT, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What DERMOL CREAM or OINTMENT looks like

Both DERMOL CREAM and OINTMENT are white in colour.

Ingredients

Active ingredient(s):

DERMOL CREAM and OINTMENT

contains 0.05% w/w of the active ingredient clobetasol 17-propionate.

DERMOL CREAM Inactive ingredients:

- propylene glycol,
- beeswax white,
- cetostearyl alcohol,
- glyceryl monostearate,
- glyceryl monostearate/PEG stearate,
- citric acid monohydrate,
- sodium citrate dihydrate,
- chlorocresol
- and purified water.

DERMOL OINTMENT Inactive ingredients:

- sorbitan sesquioleate,
- propylene glycol
- and white soft paraffin.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

DERMOL CREAM and OINTMENT are supplied in New Zealand by:

Viatrix Ltd,
PO Box 11-183,
Ellerslie,
Auckland
www.viatrix.co.nz
Telephone: 0800 168 169

Date of Preparation

01 September 2022
(Based on datasheet dated 01 September 2022).

DERMOL® is a Viatrix company trade mark.