

# NEW ZEALAND CONSUMER MEDICINE INFORMATION

## DERMOL

*Clobetasol propionate 0.05% w/w Cream and Ointment*



### What is in this leaflet

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.** You may want to read it again.

### What DERMOL CREAM or OINTMENT is used for and how it works

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 inflammation in the affected area which helps to reduce redness and itchiness caused by the skin disease.

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.

There is no evidence that DERMOL CREAM or OINTMENT is addictive.

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, short 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 is not recommended on children under one year of age.**

Do not use DERMOL CREAM or OINTMENT after the expiry date (EXP) printed on the pack.

Do not use DERMOL CREAM or OINTMENT if the packaging is torn or shows signs of tampering.

Do not let the cream or ointment enter your eyes.

#### ***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 a skin disease, 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.

#### ***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.

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

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## How to use your DERMOL CREAM or OINTMENT properly

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

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.**

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.**

### *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.

Applying your medicine at the same time each day may help you to remember to use it regularly. If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

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## While you are using DERMOL CREAM or OINTMENT

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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 a surgery, tell the surgeon or anaesthetist that you are using DERMOL CREAM or OINTMENT.

If you are going to have any blood tests, tell your doctor that you are using DERMOL CREAM or OINTMENT.

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

If you use DERMOL CREAM or OINTMENT on the eyelids, be careful to avoid contact with the eyes.

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

Visit your doctor regularly so they can check on your progress, especially if your doctor has prescribed DERMOL for psoriasis.

Do NOT give this medicine to anyone else, even if his or her symptoms seem similar to yours.

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## Side effects

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Most people find that if they apply the cream or ointment correctly they will not experience any side effects. All medicines can however, have some unwanted effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

### **Tell your doctor if you notice any of the following effects:**

- rash, inflammation or redness of the skin
- burning, pain, irritation or itching of the skin
- dry skin or skin wrinkling
- thinning of the skin and stretch marks
- changes in hair growth and changes in the colour of your skin
- blood vessels that are close to the skin surface, becoming more visible
- weight gain, rounding of the face and high blood pressure
- cloudy vision or increased pressure in the eye
- your skin condition becomes pimply
- increased severity in other untreated skin infections
- acne.
- blurred vision.

Applying DERMOL over long periods of time, or using more than the recommended dose, or applying it under and 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.**

The list of side effects is not complete. If you experience any of these side effects, or any other undesired effect please tell your doctor or pharmacist.

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

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## **In case of overdose**

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

**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.

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## **Storage conditions**

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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 store the DERMOL CREAM or OINTMENT, or any other medicine, in the bathroom or near a sink.

## **Disposal**

If your doctor tells you to stop using the DERMOL CREAM or OINTMENT or if it has passed the expiry date, ask your pharmacist

what to do with the remaining medicine.

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## **Product Description**

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### ***What DERMOL CREAM or OINTMENT looks like***

Both DERMOL CREAM and OINTMENT are white in colour

DERMOL CREAM and OINTMENT contains 0.05% w/w of the active ingredient clobetasol 17-propionate.

Each Cream also contains propylene glycol, beeswax white, cetostearyl alcohol, glyceryl monostearate, glyceryl stearate/ PEG stearate, citric acid anhydrous, sodium citrate dihydrate, chlorocresol and purified water.

Each Ointment also contains sorbitan sesquioleate, propylene glycol and white soft paraffin.

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## **If you want to know more**

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

### ***Who supplies this medicine***

Distributed in New Zealand by:

Mylan New Zealand Ltd,  
PO Box 11183,  
Eilerslie,  
Auckland.

Telephone: (09) 579 2792

### ***Date of information***

11 June 2018 (Based on datasheet dated 11 June 2018)