NEW ZEALAND CONSUMER MEDICINE INFORMATION

DERMOL®

Clobetasol propionate Scalp Lotion 0.05% w/w



Please read this leaflet carefully before you start using DERMOL Scalp Lotion.

This leaflet answers some common questions about DERMOL Scalp Lotion.

It does not contain all the available information. 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 you using DERMOL Scalp Lotion against the benefits they expect it will 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 Scalp Lotion is used for

DERMOL Scalp Lotion is used to treat conditions of the scalp, such as psoriasis and eczema.

DERMOL Scalp Lotion contains the active ingredient clobetasol propionate. It belongs to a group of medicines called 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).

Your doctor may have prescribed this medicine for another reason.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

This medicine is available only with a doctor's prescription.

Before you use DERMOL Scalp Lotion

When you must not use it

Do not use DERMOL Scalp Lotion if you have an allergy to:

- any medicine containing clobetasol propionate
- any of the ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include: 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.
- If you have an infection of the scalp

DERMOL Scalp Lotion should not be used on children less than one year old. Safety and effectiveness in children younger than 1 year have not been established.

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 start to use it

Tell your doctor if you:

- have had an allergic reaction to any other medicine used to treat your current condition or to any other cream, ointment or scalp application.
- are pregnant, plan to become pregnant, or are breastfeeding.
- require treatment for a skin condition on your face.
- have broken or infected skin.
- have any other skin problems or conditions, e.g. psoriasis.
- are a current smoker.
- 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 Scalp Lotion with these medicines may result in serious infections.
- experience newly developed bone pain or worsening of previous bone symptoms during a treatment with DERMOL Scalp Lotion especially if you have been using DERMOL Scalp Lotion 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 Scalp Lotion

Taking other medicines

Tell your doctor or pharmacist if you are using or taking any other medicines, including medicines that you buy without a

prescription from your pharmacy, supermarket or health food shop.

You should also tell any health professional who is prescribing a new medication for you that you are using DERMOL Scalp Lotion.

Some medicines may interfere with DERMOL Scalp Lotion. 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 Scalp Lotion 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 and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

How to use DERMOL Scalp Lotion

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 bottle, ask your doctor or pharmacist for help.

How much to use

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

When to use it

For adults, the elderly and children over 1 year, DERMOL Scalp Lotion is usually applied to the scalp two times a day (once in the morning and once at night)

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

Continue using your medicine for as long as your doctor tells you.

Duration of treatment will depend on your condition and can vary between a few days to a longer period of time. If your scalp condition does not clear within a few weeks, tell your doctor.

Children should not use DERMOL Scalp Lotion for longer than a few days. It should not be used on children under 1 year.

Stop using DERMOL Scalp Lotion once your skin condition has cleared.

If you forget to use it

If you forget to apply it, just apply it as soon as you remember, then apply it again as you would normally. **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 Scalp Lotion

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are using DERMOL Scalp Lotion.

Tell any other doctors, dentists, and pharmacists who treat you that you are using this medicine. If you are going to have surgery, tell the surgeon or anaesthetist that you are using this medicine. It may affect other medicines used during surgery.

If you become pregnant while using this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are using this medicine. 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 Scalp Lotion for psoriasis.

Wash your hands after applying DERMOL Scalp Lotion.

Avoid smoking whilst applying to the scalp. Avoid fire, flame and heat, including use of hair dryer, after application.

Things you must not do

Do not use DERMOL Scalp Lotion to treat any other complaints or skin conditions unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not allow the scalp application to run into your eyes. If the application does accidentally enter your eyes, rinse your eye(s) thoroughly with water.

Things to be careful of

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

In case of overdose

If you use too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON

or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have used too much DERMOL Scalp Lotion. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using DERMOL Scalp Lotion.

This medicine helps most people with scalp 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 this application correctly, they will not experience any side effects. Applying DERMOL Scalp Lotion 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:

 thinning of the skin and stretch marks

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

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.

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 Scalp Lotion

Storage

Keep your scalp lotion in the bottle until it is time to use it.

If you take the scalp lotion out of the bottle it may not keep well.

Keep your scalp lotion in a cool dry place where the temperature stays below 25°C. Keep away from fire, flame or heat. Do not leave product in direct sunlight.

Do not store DERMOL Scalp Lotion 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-anda 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 it looks like

Dermol Scalp Lotion is an almost clear, colourless liquid.

Ingredients

Active ingredient(s):
DERMOL Scalp Lotion contains
0.05% w/w of clobetasol propionate

Inactive ingredients:
DERMOL Scalp Lotion also contains also contains:

as the active ingredient.

- Carbomer 934P
- Isopropyl alcohol
- Sodium hydroxide
- Purified water

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 Scalp Lotion is supplied in New Zealand by:

Viatris Ltd, PO Box 11-183, Ellerslie, Auckland www.viatris.co.nz

Telephone: 0800 168 169

Date of Preparation

06 December 2021 (Based on datasheet dated 06 December 2021).

DERMOL® is a Viatris company trade mark.