

Package leaflet: Information for the user

Dermovate® Scalp Application 0.05% w/v Cutaneous Solution

(clobetasol propionate)

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- * Keep this leaflet. You may need to read it again.
- * If you have any further questions, ask your doctor or pharmacist.
- * This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- * If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- * In this leaflet, Dermovate Scalp Application 0.05% w/v Cutaneous Solution will be called Dermovate.

What is in this leaflet:

- 1 What Dermovate is and what it is used for
- 2 What you need to know before you use Dermovate
- 3 How to use Dermovate
- 4 Possible side effects
- 5 How to store Dermovate
- 6 Contents of the pack and other information

1 What Dermovate is and what it is used for

Dermovate contains the active substance clobetasol propionate which belongs to a group of medicines called corticosteroids. It helps to reduce redness, swelling and irritation of the scalp. (These should not be confused with "anabolic steroids" misused by some body builders and taken as tablets or injections).

Dermovate is used to help reduce the redness and itchiness of certain scalp problems in adults, the elderly and children over the age of 1 year. These include frequently relapsing dermatoses and psoriasis (thickened patches of inflamed, red skin, often covered by silvery scales) that have not responded to milder steroid creams, ointments, lotions or scalp applications.

2 What you need to know before you use Dermovate

Do not use Dermovate:

- * if you are allergic (hypersensitive) to clobetasol propionate or any of the other ingredients of Dermovate (listed in Section 6).
- * if you have a skin infection on your scalp
- * on a child under the age of 1 year.

Do not use if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using Dermovate.

Warnings and precautions

Talk to your doctor or pharmacist before using Dermovate if:

- * you have previously had an allergic reaction with another steroid.
- * your doctor has directed you to use an airtight dressing, as dressings make it easier for the active ingredient to pass through the skin. It is possible to accidentally end up using too much and the following symptoms may occur; increased weight, moon face/rounding of the face, skin thinning, changes to the colour of your skin, increased body hair, worsening of condition, pustular psoriasis (if you have psoriasis you may get raised bumps with pus under the skin).
- * you are applying the liquid under an airtight dressing, make sure that the skin is cleansed before a fresh dressing is applied to prevent infections.
- * you have psoriasis, your doctor will want to see you more often.
- * you are using this for a prolonged period of time there is a possibility you may develop a cataract (clouding of the eye's lens).
- * an infection develops during the use of this medicine talk to your doctor or pharmacist.

Only use Dermovate for as long as your doctor recommends. If your condition does not improve within 2 to 4 weeks of treatment, speak to your doctor.

Contact your doctor if you experience blurred vision or other visual disturbances.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using this medicine.

Children

- * Do not use this medicine on a child under the age of 1 year.
- * Do not use more than is needed on the scalp of a child over the age of 1 year.
- * Avoid continuous treatment for a long period of time in infants and children over the age of 1 year, with or without an occlusive dressing as adrenocortical suppression (where the body produces lower levels of the hormone cortisol than normal) and growth retardation may occur.

Other medicines and Dermovate

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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

- * ritonavir and Itraconazole.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

3 How to use Dermovate

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Using this medicine

- * You usually put Dermovate on your scalp in the morning and at night, or as directed by your doctor. This should be stopped once the problem is under control.
- * For use on your skin of your scalp only.
- * Do not use it more often than prescribed or use it for a long time (such as every day for many weeks or months). If you need treatment for a long time, your doctor may decide you need to use a milder treatment.
- * If directed to cover the treated area with a dressing always clean the skin before putting on a fresh dressing, to help prevent infection of the skin beneath the dressing.
- * Be very careful not to get the liquid in your eyes. Do not touch your eyes until you have washed your hands.
- * If you are applying the scalp application on someone else make sure you wash your hands after use or wear disposable plastic gloves.
- * If you wash or shampoo your hair it should be dried before applying Dermovate
- * Due to the flammable nature of Dermovate you should avoid smoking or being near an open flame while you're applying it and immediately after you use it.

Guidance on how to apply the liquid

- 1 Wash your hands.
- 2 Unscrew the bottle cap and place the nozzle directly on the scalp.
- 3 Gently squeeze the bottle to cover the area with a thin and even layer of liquid. You can rub this liquid in, but you don't have to.
- 4 Your scalp will feel cool until the liquid has dried.
- 5 Wash your hands again.

Use in children

- * Do not use this medicine on children under the age of 1 year.
- * Do not use more than is needed on the scalp of a child over the age of 1 year.
- * A course of treatment for an infant or child, over the age of 1 year, should not be used continuously for a long period of time, with or without an occlusive dressing, as adrenocortical suppression (where the body produces lower levels of the hormone cortisol than normal) may occur. Your doctor may want to see the child every week, whilst using the scalp application.

If you use more Dermovate than you should

If by mistake on a few occasions you use more than you should, do not worry. If you continue to use too much over a period of time you may develop symptoms such as: stretch marks, the appearance of blood vessels under the surface of your skin increased body hair, changes to the colour of your skin, skin thinning, weight gain, moon face/rounding of the face. If any of these symptoms occur or you think you have used too much of this medicine talk to your doctor or go to hospital as soon as possible. If you accidentally swallow Dermovate, it could make you ill. Rinse your mouth out with plenty of water and contact your doctor or pharmacist for advice.

If you forget to use Dermovate

If you forget to apply your scalp application, apply it as soon as you remember. If it is close to the time you are next meant to apply it, wait until this time.

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

Package leaflet: Information for the user (continued)**Dermovate® Scalp Application 0.05% w/v Cutaneous Solution**

(clobetasol propionate)

If you stop using Dermovate

If you use Dermovate regularly make sure you talk to your doctor before you stop using it.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop using Dermovate and tell your doctor as soon as possible if:

* You find that your skin problem gets worse, becomes swollen during treatment or you have the following very rare symptoms at the site of application:

- redness
- rash
- itching
- pale red raised bumps (hives)
- skin burning
- contact dermatitis

You may be allergic to the scalp application, have an infection or need other treatment.

Other side effects you may notice when using Dermovate include:

Common: may affect up to 1 in 10 people

- * itchy skin
- * local skin burning or pain

Uncommon: 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: may affect up to 1 in 10,000 people

Use of Dermovate 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/pain
- * 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)
- * 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.

Not Known: frequency cannot be estimated from the available data

- * blurred vision.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Dermovate

- * Keep this medicine out of the sight and reach of children.
- * Do not use this medicine after the expiry date which is stated on the bottle label or carton after (EXP). The expiry date refers to the last day of that month.
- * Do not store above 25°C.
- * Contents are flammable. Keep away from all sources of fire, flame and heat. Do not leave in direct sunlight.
- * Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6 Contents of the pack and other information**What Dermovate Scalp Application 0.05% w/v Cutaneous Solution contains**

Each 10ml contains 5mg of clobetasol propionate (0.05%w/v)

- * The other ingredients are isopropyl alcohol, carbomer 980 NF, sodium hydroxide and purified water.

What Dermovate Scalp Application 0.05% w/v Cutaneous Solution looks like and contents of the pack

Within each carton is a specially designed plastic bottle with a nozzle and cap that contains 100 ml of a colourless, clear to slightly hazy, slightly viscous solution.

The Parallel Product Authorisation Holder is:

LTT Pharma Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.

Repackaged by:

Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.

The manufacturer is:

Aspen Bad Oldesloe GmbH, Industriestrasse 32-36, 23843 Bad Oldesloe, Germany.

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POM PPA1562/093/001 Dermovate Scalp Application 0.05% w/v Cutaneous Solution

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Is this leaflet hard to see or read?

Phone LTT Pharma Limited,

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for help.