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IMPORTANT

GSK LOC is responsible to approve the change documentation, artwork brief and final artwork, ensuring that it is accurate, consistent and complete.

Artwork Studio is responsible for site technical requirements and pre-press suitability.

GSK Market is responsible to advise SDC when changes required impact the following:

Formulation

Tablet embossing

Storage conditions

Shelf Life

NOTE TO MARKET

Local approvers must ensure that trade mark and copyright statements included in the brief comply with guidance provided by Legal: Global Trade Marks.

ASPEN BAD OLDESLOE

Site Additional Artwork Information Panel

Production Site: ASPEN\_BAD OLDESLOE\_GERMANY

Superseded Manufacturing Site Number: N/A

12000000119202

Package Leaflet: Information for the user

GSK

DERMOVATE Scalp Application

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.

What is in this leaflet:

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

1. What Dermovate is and what it is used for

Dermovate Scalp Application (called 'Dermovate' in this leaflet) contains a medicine called clobetasol propionate. It belongs to a group of medicines called steroids. It helps to reduce swelling and irritation. Dermovate is used to help reduce the redness and itchiness of certain scalp problems. These include frequently relapsing dermatoses and psoriasis 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 this medicine (listed in Section 6)
- if you have a skin infection on your scalp
- on a child under 1 year of age.

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 your medicine if:

- you experience newly developed bone pain or worsening of previous bone symptoms during a treatment with Dermovate especially if you have been using Dermovate for a prolonged time or repeatedly.
- 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 Dermovate with these medicines may result in serious infections.
- you have previously had an allergic reaction with another steroid.
- you are applying the liquid under an airtight dressing. These dressings make it easier for the active ingredient to pass through the skin. It is possible to accidentally end up using too much. Do not bandage or otherwise cover the treated scalp area, unless directed to do so by your doctor.
- if directed to cover the treated area with a 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 applying the liquid to broken, damaged or thin skin.
- you are applying to a large surface area.

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

If an infection develops during the use of this medicine talk to your doctor or pharmacist.

Be very careful not to get the liquid in your eyes.

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.
- Avoid continuous treatment for a long period of time in children over the age of 1 year, as their skin is thinner than adults and as a result may absorb larger amounts.
- Use on children should be limited to a few days and reviewed weekly.
- Dressings or bandages should not be used on children where the scalp application is applied.

Other medicines and Dermovate

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicine, especially if you are taking ritonavir and itraconazole medications.

Pregnancy, breast-feeding and fertility

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

3. How to use Dermovate

Always use this medicine exactly as your doctor 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. This may be reduced as your scalp problem begins to get better, or stopped when it is better.
- 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.
- The germs that cause infections like warm and moist conditions under dressings. If directed to cover the treated area with a dressing, always clean the skin before a fresh dressing is put on 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 wash or shampoo your hair it should be dried before applying the liquid.
- If you are applying the scalp application on someone else make sure you wash your hands after use or wear disposable plastic gloves.
- This product is flammable. Keep the liquid away from open fire and flames and all sources of ignition, including smoking, during application and immediately after you've used it.
- Do not dry your hair with a hairdryer.

Guidance on how to apply the liquid

- Wash your hands.
- Unscrew the bottle cap and place the nozzle directly on the scalp that needs treating.
- 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. Your scalp will feel cool until the liquid has dried.
- Wash your hands again.
- Do not exceed the prescribed amount.

Use in children

- Do not use this medicine on children under 1 year of age.
- It is especially important in children not to exceed the prescribed amount.
- A course of treatment for a child should not normally last more than a few days, unless your doctor has told you to use it for longer. The doctor may want to see the child every week whilst using Dermovate scalp application.

If you use more Dermovate than you should

If you apply too much or if accidentally swallowed, it could make you ill. Talk to your doctor or go to hospital as soon as possible.

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 a missed dose.

If you stop using Dermovate

If you use Dermovate regularly make sure you talk to your doctor before you stop using it as your condition may get worse if stopped suddenly. 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 immediately if:

- you find that your scalp problem gets worse, you develop a generalised rash or your skin becomes swollen during treatment. You may be allergic to the scalp application, have an infection or need other treatment.
- you have psoriasis and get raised bumps with pus under the skin. This can happen during or after the treatment and is known as pustular psoriasis.

Other side effects you may notice when using Dermovate include: Common (may affect up to 1 in 10 people)

- a feeling of burning, pain, irritation or itching where the scalp application is applied.

Uncommon (may affect up to 1 in 100 people)

- skin thinning, this may cause stretch marks
- blood vessels under the surface of your skin may become more noticeable.

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)
- vision problems caused by detachment of the retina in the eye (central serous chorioretinopathy)
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. To report Product Complaint/s or Adverse Event/s associated with the use of GSK product/s, please contact us via: [gulf.safety@gsk.com](mailto:gulf.safety@gsk.com).

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Dermovate

- Keep out of the 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.
- Do not use this bottle for more than 3 months after first opening it.
- Keep the container tightly closed when not in use. 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 contains

- The active ingredient is clobetasol propionate. Each 1 g contains 0.5 mg of clobetasol propionate (0.05% w/w).
- The other ingredients are carbomer, isopropyl alcohol, sodium hydroxide and purified water

What Dermovate looks like and contents of the pack

Within each carton is a specially designed plastic bottle with a nozzle and cap that contains 25 ml of a sticky liquid.

Manufacturer:

Aspen Bad Oldesloe GmbH, Bad Oldesloe, Germany

Marketing Authorization Holder:

Glaxo Wellcome UK Limited, GSK Medicines Research Centre, Gunnels Wood Road, Stevenage, Hertfordshire SG1 2NY, UK

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THIS IS A MEDICAMENT

Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.

Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.

- The doctor and the pharmacist are the experts in medicines, their benefits and risks.

- Do not by yourself interrupt the period of treatment prescribed.

- Do not repeat the same prescription without consulting your doctor.

- Keep all medicaments out of the reach of children.

Council of Arab Health Ministers,

Union of Arab Pharmacists.

