

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986**

The medicine is dispensed with a physician's prescription only

Dermovate Scalp Application

Clobetasol propionate (0.05% w/w)

Each 1 gram contains 0.5 mg clobetasol propionate (0.05% w/w).

The list of additional ingredients is detailed in section 6.

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the physician or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

The medicine is not intended for children under 1 year of age.

1. WHAT IS THE MEDICINE INTENDED FOR?

Dermovate Scalp Application is used to treat inflammatory conditions responsive only to corticosteroids.

It contains a medicine called clobetasol propionate. It belongs to a group of medicines called steroids.

Therapeutic group

Corticosteroids

2. BEFORE USING THE MEDICINE

Do not use the medicine:

- if you are sensitive (allergic) to clobetasol propionate or to any of the additional ingredients contained in the medicine, as listed in section 6.
- if you have a skin infection on the scalp.
- on children under 1 year of age.

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

Special warnings regarding use of the medicine

Before treatment with Dermovate Scalp Application, tell the physician if:

- You experience newly developed bone pain or worsening of previous bone symptoms during treatment with Dermovate especially if you have been using Dermovate for a long time or have used it repeatedly.
- You use other oral/topical medication containing corticosteroids or medication intended to regulate your immune system (e.g., for autoimmune disease or after a transplantation). Combining Dermovate with these medicines may cause serious infections.
- You have previously had an allergic reaction to another steroid.
- You are applying the solution under an airtight dressing. These types of dressings make the absorption of the active ingredient through the skin easier and it is possible to accidentally end up using too high a dosage of

the solution. Do not bandage or otherwise cover the treated scalp area, unless you received explicit instruction from the physician.

- You received instruction to cover the treated area with a dressing, make sure that the skin is clean before applying a fresh dressing, to avoid infections.
- You have psoriasis, your physician will want to see you more often.
- You are applying the solution on broken, damaged or thin skin.
- You are applying the solution to a large skin area.

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

If an infection develops while using the medicine, consult the physician or pharmacist.

Be very careful not to get the solution come into contact with your eyes.

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

Children

- Do not use this medicine in children under 1 year of age.
- Avoid extended use in children over the age of 1, as their skin is thinner than that of adults and, as a result, can absorb a larger amount of the solution.
- Use in children must be limited to a few days and be accompanied by a weekly exam.
- In children, do not use dressings and patches on the site where the scalp application is applied.

Additional warnings:

- Contains inflammable substance; do not light a cigarette or come into contact with fire until the preparation has completely dried.

If you are taking, have recently taken or might take other medicines, including non-prescription medicines and nutritional supplements, tell the physician or pharmacist. Especially if you are taking ritonavir or itraconazole medications.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, or think you may be pregnant or if you are planning to become pregnant, consult your pharmacist or physician before taking this medicine.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the physician's instructions.

Check with the physician or pharmacist if you are not sure.

The dosage and treatment regimen will be determined by the physician only.

The recommended dosage is usually:

- Application of Dermovate Scalp Application on your scalp in the morning and at night. The dosage may be reduced when your scalp problem begins to improve, or will be discontinued when the problem improves.
- For use on the skin of your scalp only.
- Do not use Dermovate Scalp Application more often than prescribed for you or use it for a prolonged period (e.g., every day for many weeks or months). If you need prolonged treatment, your physician can decide that you need a milder treatment.
- The bacteria that cause infection thrive in warm and moist conditions that exist under dressings. If you were instructed to cover the treated area with a dressing, always clean the skin before applying a clean dressing to prevent infection of the skin under the dressing.
- Be very careful not to let the solution get into your eyes. Do not touch your eyes until you have washed your hands.
- If you wash or shampoo your hair, it needs to dry before applying the solution.
- If you are applying Dermovate Scalp Application on someone else, make sure you wash your hands after use or wear disposable plastic gloves.
- **Caution! Contains inflammable substance. Avoid exposure of the solution to an open fire, to flames and to any other ignition source, including smoking when applying or immediately after applying the solution.**
- **Do not dry your hair with a hairdryer.**

Instructions for applying the solution

1. Wash your hands.
2. Open the bottle cap and place the nozzle directly on the scalp that needs treating.
3. Gently squeeze the bottle to cover the area with a thin and even layer of solution.
4. You can rub the solution in, but you do not have to.
5. Your scalp will feel cool until the solution has dried.
6. Wash your hands again.

Do not exceed the recommended dose.

Do not swallow.

For external use only.

Use in children

- Do not use this medicine in children under 1 year of age.
- In children, it is extremely important not to exceed the prescribed amount.
- The duration of treatment for a child should not usually last more than a few days, unless your physician has told you to use the solution for longer. The physician may want to see the child every week during the course of treatment with Dermovate Scalp Application.

If you accidentally took a higher dosage

If you applied too much, or if you accidentally swallowed the scalp application, you may get sick. Refer to your physician or proceed to a hospital as soon as possible.

If a child accidentally took the medicine, immediately refer to a physician or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine

If you forgot to apply the solution on the scalp, apply it as soon as you remember. If it is almost time for the next time you planned to apply it, wait until that time.

Do not apply more Dermovate Scalp Application to compensate for the missed dose.

Adhere to the treatment regimen as recommended by the physician.

Even if there is an improvement in your health, do not discontinue treatment with the medicine without consulting with the physician.

If you stop taking the medicine

If you use Dermovate Scalp Application regularly, be sure to consult your physician before you stop using it, since your condition may worsen if the treatment is stopped abruptly.

Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the physician or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Dermovate Scalp Application may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Stop using Dermovate Scalp Application and refer to the physician immediately if:

- you discover that your scalp problem is getting worse, you develop a generalized rash or your skin becomes swollen during treatment. You may be allergic to Dermovate Scalp Application, have an infection or need other treatment.
- you have psoriasis and develop bumps with pus under the skin. This can happen during or after the treatment and is known as pustular psoriasis.

Additional side effects you may notice when using Dermovate Scalp Application include:

Common side effects (may occur in up to 1 in 10 people)

- a feeling of burning, pain, irritation or itching in the area where the solution is applied.

Uncommon side effects (may occur in up to 1 in 100 people)

- skin thinning, which may cause stretch marks

- blood vessels under the surface of your skin may become more noticeable.

Very rare side effects (may occur in up to 1 in 10,000 people)

Use of Dermovate Scalp Application 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 color of the skin
- increased amount of body hair
- hair loss/lack of hair growth/damaged looking hair.

Other very rare skin side effects that may occur:

- allergic reaction at the site of application
- worsening of skin condition
- application site irritation or 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, pay attention to the following signs:

- slowed weight gain
- slowed growth.

Very rare side effects that may show up in blood test results or when your physician gives you a medical examination:

- a decrease in the level of the hormone cortisol in your blood
- increased level of sugar in the 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 the medical examination to diagnose this condition.

Side effect of unknown frequency

- blurred vision.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult with the physician.

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
<https://sideeffects.health.gov.il/>

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the sight and reach of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the physician.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- For use within three months from opening.
- Keep the bottle tightly closed when not in use.
- The contents are inflammable. Keep away from any source of fire, flames or heat. Do not leave exposed to direct sunlight.
- Do not throw away any medicine into the wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. This will help protect the environment.

6. FURTHER INFORMATION

- In addition to the active ingredient, the medicine also contains – isopropyl alcohol, carbomer, sodium hydroxide and purified water.
- What the medicine looks like and the contents of the package – Each carton package contains a plastic bottle with a nozzle and cap that contains 25 or 100 ml of a sticky liquid.
Not all pack sizes may be marketed.
- Manufacturer: Aspen Bad Oldesloe GmbH, Bad Oldesloe, Germany.
- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 046-92-23798.

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