**Package leaflet: Information for the user**

**DiproSalic® Scalp Application 0.05% w/w / 2% w/w, cutaneous solution**
betamethasone (as dipropionate 0.064%)/salicylic acid

**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**



## 1. What Diprosalic Scalp Application is and what it is used for

Diprosalic Scalp Application contains two active ingredients, betamethasone dipropionate and salicylic acid. Betamethasone dipropionate is one of a group of medicines called topical corticosteroids. These medicines are put on the surface of the skin to reduce the redness and itchiness caused by certain skin problems. Corticosteroid creams, ointments and other topical preparations come in four different potencies or strengths. These are known as mild, moderately potent, potent or very potent. Healthcare professionals will usually refer to topical corticosteroid potency rather than strength. A potent or strong corticosteroid has a much stronger effect than a mild corticosteroid when using the same amount. The percentage of active ingredient that is sometimes included on product packaging does not indicate potency. Diprosalic is classed as a strong corticosteroid. Your healthcare professional will prescribe or advise a steroid of the appropriate potency for your condition.

Salicylic acid softens the top layer of scales on the surface of the skin, which are caused by your skin problem. This allows the betamethasone dipropionate to reach the diseased skin underneath to help heal it.

In adults and children, Diprosalic Scalp Application is used to treat skin conditions where the outer surface of the skin is covered by a layer of scales. Your scalp application will remove the layer of scales and reduce the redness and itchiness caused by your skin problem.

## 2. What you need to know before you use Diprosalic Scalp Application

**Do not use Diprosalic Scalp Application**

If you have:
- an allergy to betamethasone dipropionate, salicylic acid or any of the other ingredients in this medicine (listed in section 6).
- any other skin problem as it could make it worse especially rosacea (a skin condition affecting the face), acne, dermatitis (skin inflammation) around the mouth, genital itching, nappy rash, cold sores, chickenpox or other skin conditions.

**Warnings and precautions**

If you have psoriasis, your doctor may want to review your treatment regularly. Contact your doctor if your psoriasis gets worse or you get raised bumps filled with pus under your skin.

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

This medicine should not be used under bandages or plasters.

Side effects that may happen with inhaled or oral corticosteroids may also occur with corticosteroids used on the skin, especially in infants and children.

If you use more than the correct amount of scalp application and/or use it for longer than is recommended, it can affect the levels of certain hormones in the body, particularly in infants and children.

In adults the changes in hormone levels may lead rarely to puffiness or rounding of the face, weakness, tiredness, and dizziness when standing or sitting down.

Do not smoke or go near naked flames – risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

If there is a worsening of your condition during use consult your prescriber – you may be experiencing an allergic reaction, have an infection or your condition requires a different treatment.

If you experience a recurrence of your condition shortly after stopping treatment, within 2 weeks, do not restart using the scalp application without consulting your prescriber unless your prescriber has previously advised you to do so. If your condition has resolved and on recurrence the redness extends beyond the initial treatment area and you experience a burning sensation, please seek medical advice before restarting treatment.

**Children**

If you use more than the correct amount of scalp application and/or use it for longer than is recommended, it can affect your child's hormones. Rarely this may lead to:

- Delayed growth and development
- Puffiness or rounding of the face
- A build-up of pressure around the brain which can produce
    - a bulging of the fontanelle (the soft spot in the top of the skull) in infants
    - a constant thumping headache
    - blurred vision or other visual disturbances

**Pregnancy, breast-feeding and fertility**

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 taking this medicine.

## 3. How to use Diprosalic Scalp Application

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

**Recommended dose**

Usually for adults and children, a few drops of Diprosalic Scalp Application should be gently and completely rubbed into the affected area of scalp twice a day.

**You should always follow these instructions when using Diprosalic Scalp Application:**
- Only use this scalp application on your scalp.
- Do not use a large amount of scalp application for a long time (for example every day for many weeks or months).
- Avoid getting the scalp application in your eyes or inside your nose or mouth.

**Use in children**
Use as stated above. Do not use this scalp application on your child's scalp for more than 5 days.

**If you use more Diprosalic Scalp Application than you should**
If you (or somebody else) accidentally swallows the scalp application, it should not cause any problems. However, if you are worried, you should see your doctor. If you use the scalp application more often than you should, or more than prescribed, it can affect some of your hormones. In children this may affect their growth and development. It also may cause you to feel and/or be sick and to hear ringing in your ears. If you have not used the scalp application as you were told to do and have used it too often and/or for a long time, you should tell your doctor or pharmacist.

**If you forget to use Diprosalic Scalp Application**
If you forget to use your scalp application at the right time, use it as soon as you remember, then carry on as before.

**If you stop using Diprosalic Scalp Application**
If you have been using this medicine for a long time and your scalp problem seems to have got better, you should not suddenly stop using this medicine. If you do, you may find that your scalp becomes red and you may notice stinging and burning. To avoid this, you should speak to your doctor who will gradually reduce how often you need to use this medicine until you stop treatment altogether.

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.

Most people find that when the scalp application is used correctly, it does not cause any problems. However, if you use the scalp application more often than you should, it can cause the following:
- Thinning of the skin, stinging, blistering, peeling, swelling, itching, burning, skin rash, dryness of the skin and you may notice red marks. This can happen more easily in infants and children.
- Inflammation of the skin follicles, excessive hair growth, reduced skin pigmentation and allergic reactions.
- Dermatitis (skin inflammation), a condition brought on by the skin reacting to outside agents e.g. detergents, causing the skin to become red and itchy.
- Blurred vision

Steroid withdrawal reaction: If used over prolonged periods a withdrawal reaction, which might appear to be different from the previous condition, may occur in some patients during treatment or within days to weeks after stopping treatment, with some or all of the following features: redness of the skin which can extend beyond the initial area treated, a burning or stinging sensation, intense itching, peeling of the skin, oozing open sores.

**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. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

## 5. How to store Diprosalic Scalp Application

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 label and carton after 'EXP'. The expiry date refers to the last day of that month.

Do not store above 25°C.

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 protect the environment.

## 6. Contents of the pack and other information

**What Diprosalic Scalp Application contains**

- The active substances are betamethasone dipropionate and salicylic acid. Each gram contains 0.64 mg of betamethasone dipropionate (equivalent to 0.5 mg betamethasone) and 20 mg of salicylic acid.
- The other ingredients are disodium edetate, hydroxypropyl methylcellulose, sodium hydroxide, isopropyl alcohol and purified water.

**What Diprosalic Scalp Application looks like and contents of the pack**
Diprosalic Scalp Application is a colourless, slightly thick solution. It is available in a bottle containing 30 ml or 100 ml. Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**
The holder of the Marketing Authorisation is:
Organon Pharma (UK) Limited, Shotton Lane, Cramlington, United Kingdom, NE23 3JU.

The manufacturer is:
Cenexi HSC
2, rue Louis Pasteur
14200 Hérouville Saint-Clair
France

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