

PACKAGE LEAFLET: INFORMATION FOR THE USER

Diprosalic® 0.05% w/w + 2% w/w Scalp Application

Betamethasone (as dipropionate)/Salicylic acid

Read all of this leaflet carefully before you start using this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Diprosalic Scalp Application is and what it is used for
2. Before you use Diprosalic Scalp Application
3. How to use Diprosalic Scalp Application
4. Possible side effects
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6. Further information

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. It is classified as a “potent corticosteroid”. These medicines are put on the surface of the skin to reduce the redness and itchiness caused by certain skin problems. 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. BEFORE YOU USE DIPROSALIC SCALP APPLICATION

Do not use Diprosalic Scalp Application

- if you are allergic (hypersensitive) to betamethasone dipropionate, salicylic acid or any of the other ingredients in Diprosalic Scalp Application.
- on 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.

Pregnancy and breast-feeding

You should tell your doctor if you are pregnant or breast-feeding, before you start using Diprosalic Scalp Application.

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

3. HOW TO USE DIPROSALIC SCALP APPLICATION

Always use Diprosalic Scalp Application exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

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 this scalp application on your child's scalp for more than 5 days.
- 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.

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, 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.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Diprosalic Scalp Application 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 skin thinning, stinging, blistering, peeling, swelling, itching, burning, skin rash, dryness of the skin, inflammation of the hair follicles, excessive hair growth, reduced skin pigmentation and allergic skin reactions and you may notice red marks. This can happen more easily in infants and children. Also, the scalp application may cause blurred vision or another skin condition called dermatitis, a condition brought on by the skin reacting to outside agents e.g. detergents, causing the skin to become red and itchy. If you are worried by these or any other effects, you should tell your doctor or pharmacist.

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 HPRC 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 DIPROSALIC SCALP APPLICATION

Keep out of the reach and sight of children.

Do not use Diprosalic Scalp Application after the expiry date which is stated on the carton and bottle after EXP. The expiry date refers to the last day of that month.

Do not store the scalp application above 25°C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Diprosalic Scalp Application contains

- The active substances are 0.05% w/w betamethasone (as dipropionate) and 2% w/w salicylic acid.

- The other ingredients are disodium edetate, hypromellose, 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 bottles containing 30ml and 100ml.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The holder of the Marketing Authorisation is:

Organon Pharma (Ireland) Limited

2 Dublin Landings

North Wall Quay - North Dock

Dublin, D01 V4A3, Ireland

The manufacturer is:

Schering-Plough Labo NV,

Heist-op-den Berg, Belgium.

or

Cenexi HSC

2 rue Louis Pasteur

14200 Hérouville-Saint-Clair, France.

This leaflet was last revised in July 2021

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