

Package leaflet: Information for the user

**Diprosalic® 0.05%w/w +
3%w/w Ointment**

(betamethasone dipropionate/
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.

The name of your medicine is Diprosalic® 0.05%w/w + 3%w/w Ointment, but it will be referred to as Diprosalic throughout this leaflet.

What is in this leaflet:

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

1. What Diprosalic is and what it is used for

Diprosalic 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 is used to treat skin conditions where the outer surface of the skin is covered by a layer of scales. Your ointment 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

Do not use Diprosalic

- if you are allergic to betamethasone dipropionate, salicylic acid or any of the other ingredients in this medicine (listed in section 6).
- 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.

Warnings and precautions

Talk to your doctor or pharmacist before using diprosalic ointment.

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.

Children

If the ointment is used more often than it should, or more than prescribed, it can affect some of your child's hormones. This may affect their growth and development.

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

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 thin layer of Diprosalic should be gently rubbed into the affected area of skin twice a day.

You should always follow these instructions when using Diprosalic:

- Do not use the ointment on your face for more than 5 days.
- Do not use a large amount of ointment on large areas of the body for a long time (for example every day for many weeks or months).
- Avoid getting the ointment in your eyes.

Use in children

Use as stated above. Do not use this ointment on any part of your child's body for more than 5 days. Do not put the ointment under your child's nappy, as this makes it easier for the active ingredients of the medicine to pass through the skin and possibly cause some unwanted effects.

If you use more Diprosalic than you should

If you (or somebody else) accidentally swallow the ointment, it should not cause any problems. However, if you are worried, you should see your doctor. If you use the ointment more often than you should, or on large areas of your body, 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 ointment 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

If you forget to use your ointment at the right time, use it as soon as you remember, then carry on as before.

If you stop using diprosalic

If you have been using the ointment for a long time and your skin problem seems to have got better, you should not suddenly stop using the ointment. If you do, you may find that your skin becomes red and you may notice stinging or burning. To avoid this, you should speak to your doctor who will gradually reduce how often you need to use the ointment 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 ointment is used correctly, it does not cause any problems. However, if you use the ointment 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 hair follicles, excessive hair growth, reduced skin pigmentation and allergic skin reactions.
- Dermatitis (skin inflammation), a condition brought on by the skin reacting to outside agent e.g. detergents, causing the skin to become red and itchy.

Reporting side effects HPRA

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 Diprosalic

Do not store above 25°C.

Keep out of the sight and reach of children, preferably in a locked cabinet.

Do not use after the date marked on the outer carton and tube label.

6. Contents of the pack and other information

What Diprosalic contains

The ointment contains 0.05% w/w betamethasone (as dipropionate), and 3% w/w salicylic acid as the active ingredients. The other ingredients are liquid paraffin and white soft paraffin.

What Diprosalic looks like and contents of the pack

Diprosalic is a smooth, off-white ointment. It is available in tubes containing 30 g.

Manufactured by: Schering-Plough, 2 rue Louis Pasteur, 14200, Herouville Saint Clair, France.

Procured from within the EU and repackaged by PPA holder:

B&S Healthcare, Unit 4 Bradfield Road, Ruislip Middlesex, HA4 0NU, UK.

Diprosalic® 0.05%w/w + 3%w/w Ointment PPA No: 1328/75/1

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