

**Diprosalic* 0.5 mg/g – 30 mg/g Ointment**

betamethasone dipropionate and 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If any of the adverse effects become serious or if you notice any adverse effects not listed in this leaflet, please talk to your doctor or pharmacist.

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. Other information

1. What Diprosalic is and what it is used for

Diprosalic contains betamethasone dipropionate, a steroid, and salicylic acid, a substance that facilitates the passage of betamethasone dipropionate through the skin.

Diprosalic is used to treat inflammatory conditions of the skin.

2. What you need to know before you use Diprosalic**Do not use Diprosalic**

- if you are allergic (hypersensitive) to betamethasone dipropionate, salicylic acid or to any of the other ingredients of Diprosalic (listed in section 6)
- if you have ulcers on the skin
- on a wound
- on infected skin
- on acne-affected skin
- near the eyes
- on mucous membranes such as the mouth or anus.

Take special care with Diprosalic

Talk to your doctor before using Diprosalic:

- if your skin has a bacterial infection - you need to receive treatment for this infection. If the treatment does not work quickly, stop using Diprosalic.
- if you need to use the medicine for a long period of time or over a large area of the skin
- if your skin is thin or damaged
- if you are using the medicine under an occlusive dressing
- if you are a child.

Before using Diprosalic, please tell your doctor if any of the above situations applies to you or if it did in the past.

Using other medicines

If you are taking or have recently taken any other medicines, including medicines obtained without a prescription, talk to your doctor or pharmacist about it.

Pregnancy and breast-feeding

Seek advice from your doctor before using Diprosalic if you are pregnant or breast-feeding, especially if you have to use it for a long period of time or over a large area of the skin, as only your doctor can decide if you can use Diprosalic during pregnancy or while breastfeeding.

Ask your doctor or pharmacist for advice before taking any medicine.

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

3. How to use Diprosalic

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

Diprosalic is exclusively for use on the skin.

How to use Diprosalic

- Use Diprosalic twice daily, morning and evening.
- Apply a thin layer of Diprosalic to completely cover the area(s) to be treated.
- Massage gently for the medicine to penetrate into the skin so that it works properly.
- Wash your hands after applying Diprosalic.

Duration of use of Diprosalic

Your doctor will tell you how long you should use Diprosalic. This will depend on how the treatment works. The treatment should be stopped as soon as the lesions are healed.

- If no improvement is noticed, please see your doctor.
- Do not use Diprosalic for more than two weeks unless your doctor tells you to.
- As soon as the scaly layer or thickening of the skin disappears, the treatment should be continued with a steroid alone.

Always follow the doctor's recommendations.

If you use more Diprosalic than you should

If you have used more Diprosalic than you should or if you accidentally swallow the medicine (caution with children), immediately contact your doctor, or pharmacist.

The symptoms of overdose are similar to those observed in cases of too frequent applications of Diprosalic or prolonged treatment (see section "4. Possible adverse effects").

If you swallow Diprosalic or if you use it for extended periods over large areas, the salicylic acid in the medicine can cause salicylic acid poisoning. The signs of this poisoning are dizziness, nausea or vomiting, headache, or ringing in the ears. These symptoms are reversible.

If you forget to use Diprosalic

Do not use a double dose to make up for a forgotten dose.

If you stop using Diprosalic

When you stop treatment, your skin problems may return.

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

4. Possible side effects

Like all medicines, Diprosalic can cause adverse effects, although not everybody gets them all.

Allergic reactions

If you have an allergic reaction, stop using Diprosalic and see a doctor immediately.

Diprosalic is generally well tolerated. However, you could develop the following problems on the skin:

- acne
- stretch marks
- skin infections
- skin problems around the mouth
- discoloration, atrophy or softening of the skin
- inflammation of the hair roots, abnormal hair growth
- burning sensation, itching, irritation, dryness or redness of the skin ("contact dermatitis") - if there is any irritation on your skin, stop using Diprosalic.

As is the case with other steroids, in case of application of Diprosalic over a large area of the skin, application of a large amount, prolonged treatment or application under an occlusive dressing, the amount of steroid absorbed through the skin may increase, which may cause systemic adverse effects, such as swelling of the face, neck and trunk, or weight gain, or blurred vision. In children, growth may be disrupted. See your doctor if this applies to you.

Children, patients with thin or damaged skin, and patients with severe liver disease are more susceptible to adverse effects.

If you experience any of the effects listed as serious or if you notice any adverse effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Diprosalic

Keep out of the sight and reach of children.

Stored not above 30°C

Do not use Diprosalic after the expiry date which is stated on the box and label after {EXP}. The expiry date refers to the last day of that month.

Medicines should not be disposed of via main drainage or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information**What Diprosalic contains**

Diprosalic Ointment:

- The active ingredients are betamethasone dipropionate 0.64 mg/g (which is equivalent to 0.5 mg/g of betamethasone) and salicylic acid 30 mg/g.
- The other ingredients are: liquid paraffin and white soft paraffin.

What Diprosalic looks like and contents of the pack

Diprosalic Ointment: 5, 10, 15, 20, 30, 50, 100 and 500 g aluminum tubes.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

MSD Belgium BVBA/SPRL, Clos du Lynx 5, B-1200 Brussels.

Manufactured and Released by:

Schering-Plough Labo N.V., Industriepark 30, B-2220 Heist-op-den-berg, Belgium

For information about this medicine, please contact your doctor or pharmacist.

Medicinal product subject to medical prescription.

This leaflet was last revised in 10/2017.

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 reach of children.

Council of Arab Health Ministers & Union of Arab Pharmacists