



For Position Only

Package Leaflet: Information for the patient

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Diprosone* 0.5 mg/g Cream

betamethasone dipropionate



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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 Diprosone is and what it is used for
2. What you need to know before you start using Diprosone
3. How to use Diprosone
4. Possible adverse effects
5. How to store Diprosone
6. Other information

1. What Diprosone is and what it is used for

Diprosone contains betamethasone dipropionate, a steroid. Diprosone is used to treat inflammatory problems of the skin.

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

- if you are allergic (hypersensitive) to betamethasone dipropionate or to any of the other ingredients of Diprosone (listed in section 6)
- if you have ulcers on the skin
- on a wound
- on infected skin
- on acne-affected skin
- near the eyes.

Take special care with Diprosone

Talk to your doctor before using Diprosone:

- if you need to use the medicine for a long period of time or over a large area
- if your skin is thin or damaged
- if you are using the medicine under an occlusive dressing
- if you are a child.

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

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

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

Check with your doctor before using Diprosone if you are pregnant or breast-feeding, especially if you need to use it for a long period of time or apply it over a large area. You should do so because only your doctor is able to decide if you can use Diprosone during pregnancy or while breastfeeding.

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

Important information about some of the ingredients of Diprosone

- Diprosone Cream contains chlorocresol. It may cause allergic reactions.
- Diprosone Cream contains cetostearyl alcohol. It may cause local skin reactions (for example, eczema).

3. How to use Diprosone

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

Diprosone is intended exclusively for application to the skin.

How to use Diprosone

- Use Diprosone twice daily, morning and evening.
- Apply a thin layer of Diprosone 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 Diprosone.

How long should you use Diprosone?

Your doctor will tell you how long you should use Diprosone. This will depend on the results obtained. The treatment will be stopped as soon as the affected skin heals.

- If no improvement is noticed, please see your doctor again.
- Do not use Diprosone for more than two weeks unless your doctor tells you to.

Always follow your doctor's recommendations.

If you use more Diprosone than you should

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

The symptoms of overdose are similar to those observed in case of too frequent applications of Diprosone or prolonged treatment (see section "4. Possible adverse effects"). The symptoms are reversible. If necessary, your doctor will need to restore the balance of what is called "electrolytes" in your body to help control the fluid balance in your body.

If you forget to use Diprosone

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

If you stop using Diprosone

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, Diprosone can cause adverse effects, although not everybody gets them all.

Allergic reactions

If you have an allergic reaction, stop using Diprosone and see your doctor immediately.

Diprosone 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 or thinning 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 Diprosone.

As is the case with other steroids, applying Diprosone on a large area, in a large amount, over a long period of time or under an occlusive dressing, can cause the absorption of a higher amount of steroids through the skin. This may cause systemic adverse effects of steroids such as swelling of the face, neck and trunk or weight gain, or blurred vision. In children, growth may be impaired. See your doctor if you have these adverse effects.

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.

5. How to store Diprosone

Stored not above 30°C

Keep out of the sight and reach of children.

Do not use Diprosone after the expiry date which is stated on the package after {EXP}. The expiry date refers to the last day of the 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 Diprosone contains**

Diprosone Cream:

- The active ingredient is betamethasone dipropionate 0.64 mg/g (which is equivalent to 0.5 mg/g of betamethasone).
- The other ingredients are: chlorocresol, sodium dihydrogen phosphate dihydrate, phosphoric acid, white soft paraffin; liquid paraffin, cetomacrogol 1000, cetostearyl alcohol, sodium hydroxide, purified water.

What Diprosone looks like and contents of the container

Diprosone Cream: 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, 1200 Brussels, Belgium

Manufacturer 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 experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children

Council of Arab Health Ministers

Union of Arab Pharmacists