

Diprosone * 0.5 mg/g Cream
Diprosone * 0.5 mg/g Ointment

Betamethasone dipropionate

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 Diprosone is and what it is used for
2. What you need to know before you use Diprosone
3. How to use Diprosone
4. Possible side effects
5. How to store Diprosone
6. Contents of the pack and 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 to betamethasone dipropionate or to any of the other ingredients of this medicine (listed in section 6)
- if you have ulcers on the skin
- on a wound
- on infected skin
- on acne-affected skin
- near the eyes.

Warnings and precautions

Talk to your doctor or pharmacist 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
- you have a blurred vision or other visual disturbances.

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

Children

In children, the absorption capacity of corticosteroids is greater (due to the high body surface area/body weight ratio); therefore, they demonstrate greater susceptibility to systemic effects (see section 4. Possible side effects) Corticoids may affect growth hormone secretion in children; therefore, the evolution of their weight and height should be monitored.

Any of the side effects that are reported following systemic use of corticosteroids, including adrenal suppression, may also occur with topical corticosteroids, especially in infants and children.

Other medicines and Diprosone

Tell your doctor or pharmacist if you are using or have recently used or might use any other medicines.

Pregnancy and breast-feeding

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, 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.

Diprosone contains chlorocresol and cetostearyl alcohol.

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

3. How to use Diprosone

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

- Use Diprosone once to twice daily, morning and/or 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.
- Diprosone is intended exclusively for application to the skin.

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.

Use in children

Corticoids may affect growth hormone secretion in children; therefore, the evolution of their weight and height should be monitored.

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, this medicine can cause side effects, although not everybody gets them. 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.

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. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Diprosone

Keep this medicine out of the sight and reach of children.

Do not store above 30°C

Do not use this medicine after the expiry date which is stated on the package after EXP. The expiry date refers to the last day of the month.

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 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.

Diprosone Ointment:

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

What Diprosone looks like and contents of the pack

Diprosone Cream is available in aluminium tubes of 5, 10, 15, 20, 30, 50, 100 and 500 g.

Diprosone Ointment is available in aluminium tubes of 10, 15, 20, 30, 50, 100 and 500 g tubes.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Organon Belgium
Rue du Commerce 31
B-1000 Brussels, Belgium

Manufacturer and Batch releaser:

Organon Heist bv., Industriepark 30, 2220 Heist-op-den-berg,, Belgium

Medicine subject to medical prescription.

*Trademark

This leaflet was last revised in 12/2022.

(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