

PACKAGE LEAFLET: INFORMATION FOR THE USER

Diprosone 0.5 mg/g cream
Diprosone ointment, ointment 0.5 mg/g
Diprosone 0.05% lotion, lotion 0.5 mg/g
betamethasone

Read the entire 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.

- Do you have any questions? Please contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed for you only. It may harm them, even if their symptoms are the same as yours.
- If you experience any side effects listed in section 4, or if you notice any side effects not listed in this leaflet, please contact your doctor or pharmacist.
- Contents of this leaflet

What is Diprosone and what is it used for?

1. When should you not use this medicine or be extra careful?
2. How to use this medicine?
3. Possible side effects
4. How to store this medicine?
5. Contents of the pack and other information
6. Contents of the package and other information

1. WHAT IS DIPROSONE AND WHAT IS THIS MEDICINE USED FOR?

Betamethasone belongs to the corticosteroids, a group of substances that suppress inflammatory reactions. Therefore, Diprosone suppresses the symptoms of various skin conditions, which are often accompanied by itching, but without curing the actual condition. Diprosone is suitable for the treatment of certain skin conditions that are usually characterized by scaling, redness, eczema, and sometimes itching.

Since Diprosone has a high level of activity, it is classified in the group of highly potent substances.

Diprosone is prescribed by your doctor for certain skin diseases that respond favorably to local treatment with medicines containing corticosteroids. Diprosone is only used when less potent agents are insufficient.

2. WHEN SHOULD YOU NOT USE THIS MEDICINE OR BE EXTRA CAREFUL WITH IT?

When should you not use this medicine?

- You suffer from severe skin infections caused by fungi, yeasts, or bacteria, or skin infections caused by viruses, particularly chickenpox, shingles, cold sores, warts, tuberculosis of the skin, and also skin infections by parasites, such as scabies.
- In wounds and ulcers, acne, and if you show typical side effects of corticosteroids, such as stretch marks due to overstretching of the skin and skin inflammation around the mouth.

- You suffer from ichthyosis, redness and scaling of the skin of the soles at a young age, rosacea, fragility of the skin vessels, or if you have thin skin.
- You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.

When should you be extra careful with this medicine?

If your skin shows signs of irritation or allergic reactions (including hypersensitivity) as a result of using Diprosone, you should stop using it and consult your doctor.

Do not use Diprosone on facial skin, hairy skin, and the skin of the genitals unless prescribed by your doctor.

Be careful not to get Diprosone in or around your eyes.

When using Diprosone in children and teenagers, it is necessary for them to be regularly medically monitored, as this medication is absorbed through the skin and can affect growth or cause other unwanted effects.

Use under occlusion is rarely necessary. In cases where your doctor has prescribed the use of Diprosone under occlusion with plastic, on large body surfaces, or in skin folds, caution is advised as this can increase the amount absorbed, increasing the risk of local side effects or side effects throughout the body.

Consult your doctor about other medical conditions, especially if you have an infection. Contact your doctor if you experience blurred vision or other visual disturbances.

Contact your doctor or pharmacist before using this medicine.

Are you using any other medicines?

Are you using any other medicines besides Diprosone, have you recently done so, or is there a possibility that you will use other medicines in the near future? Then tell your doctor or pharmacist.

Pregnancy and breastfeeding

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine.

Diprosone belongs to the potent corticosteroids. It is known that corticosteroids can pass through the placenta.

Adverse effects cannot therefore be excluded.

You may only use Diprosone during pregnancy in consultation with your doctor.

Breastfeeding while using Diprosone is not recommended.

Driving and using machines

There is no data available on the influence of Diprosone on the ability to drive and use machines. However, an effect is not likely.

Diprosone cream contains cetostearyl alcohol and chlorocresol

Cetostearyl alcohol may cause local skin reactions, for example, inflammation of the skin. Chlorocresol may cause a hypersensitivity reaction (allergic reaction).

3. HOW TO USE THIS MEDICINE?

Always use this medicine exactly as your doctor or pharmacist has told you. If you are unsure about the correct use, contact your doctor or pharmacist.

The skin or scalp being treated should not be covered after applying Diprosone, unless prescribed by your doctor.

The recommended dosage is to apply a small amount to the affected skin once or twice a day. You should never use more than 30-60 grams (solution for cutaneous use: 30-60 ml) of this medicine per week, unless prescribed by your doctor.

Diprosone should only be used in the recommended dose. Consult your doctor if you have used Diprosone in large quantities or for a longer period than prescribed.

Seek immediate medical help if you have accidentally swallowed Diprosone.

If you notice that Diprosone is too strong or not strong enough, consult your doctor or pharmacist.

Have you used too much of this medicine?

If you have used too much Diprosone, contact your doctor or pharmacist immediately.

Did you forget to use this medicine?

If you forgot to use Diprosone as prescribed, apply the medicine as soon as possible and continue the normal dosing schedule. Do not use a double dose to make up for a forgotten dose.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

The frequencies shown in the list below are defined as follows:

Very common: occur in more than 1 in 10 users

Common: occur in less than 1 in 10 users

Sometimes: occur in less than 1 in 100 users

Rare: occur in less than 1 in 1000 users

Very rare: occur in less than 1 in 10,000 users

Unknown: frequency cannot be determined from the available data

Immune system

Very rare:

- hypersensitivity.

Hormonal system/hormone

Very rare:

- increased cortisol level in the blood which may be accompanied by, among other things, fluid retention, obesity, increased blood pressure (hypercortisolism). This can occur when Diprosone is used for a long time and in large amounts. It is expected that this can occur more quickly in toddlers and children or when occlusive dressings are used. In toddlers, the diaper can have the same occlusive effect.
- insufficient functioning of the adrenal cortex with symptoms such as fluid loss, low blood pressure, gastrointestinal complaints, and a change in skin pigmentation (adrenal insufficiency). This can occur when Diprosone is used for a long time.

Eyes

Very rare:

- increase in internal eye pressure (intraocular pressure), greater risk of cataracts.

Unknown:

- blurred vision.

Blood vessels

Very rare:

- dilation of blood vessels (telangiectasia). This can occur when Diprosone is used for a long time and intensively, particularly when occlusive dressings are used or it concerns skin folds.

Skin

Common:

- local burning sensation of the skin and itching (pruritus). These occur when Diprosone is used for a long time and intensively, especially when occlusive dressings are used or it concerns skin folds.

Very rarely:

- thinning of the skin (skin atrophy), discoloration of the skin (depigmentation), pinpoint bleeding (purpura), streaky skin stretch marks (striae), excessive hair growth (hypertrichosis), aggravated form of the skin condition. These occur when Diprosone is used for a long time and intensively, especially when occlusive dressings are used or it concerns skin folds.

Further allergic skin inflammation due to contact with irritating substances or substances for which there is hypersensitivity (allergic contact dermatitis), scaly eczema with bumps (psoriasis pustulosa) or skin disease with symptoms of redness, dryness, burning sensation of the skin, especially around the mouth (rosacea-like and perioral dermatitis with and without thinning of the skin).

- the recurrence of the symptoms of the original condition in an intensified manner (rebound phenomena). This occurs with long-term use of Diprosone in chronic skin diseases and can lead to steroid dependence.
- with improper use, bacterial, parasitic, fungal, and viral infections can be masked and/or worsened.
- the local formation of orange-yellow granules (milia) due to blockage of the skin.

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb, website: www.lareb.nl. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. HOW TO STORE THIS MEDICINE?

Keep out of the sight and reach of children.

Store Diprosone ointment below 30°C. After opening, it is usable for 3 months.

For Diprosone cream, no special storage conditions apply. Diprosone cream from Spain is usable for 3 months after opening.

Diprosone lotion should not be used 12 weeks after opening.

Do not use this medicine after the expiry date. It can be found on the label on the packaging after 'EXP:'. It includes a month and a year. The last day of that month is the expiry date.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will then be destroyed responsibly and will not end up in the environment.

6. CONTENTS OF THE PACKAGING AND OTHER INFORMATION

What substances are in this medicine?

- The active substance in this medicine is betamethasone dipropionate 0.64 mg/g, corresponding to 0.5 mg/g betamethasone.
- The other substances (excipients) in this medicine are:
Diprosone cream: petrolatum, liquid paraffin, cetomacrogol (1000), cetostearyl alcohol, sodium phosphate, phosphoric acid, and purified water, with chlorocresol as a preservative. The product from Spain also contains sodium hydroxide (for pH adjustment).
Diprosone ointment: white petrolatum and liquid paraffin.
Diprosone lotion: carbomer, sodium hydroxide, isopropanol, and purified water.

What does Diprosone look like and how much is in a package?

Diprosone cream is delivered in tubes with a plastic screw cap containing 30 or 50 grams.

Diprosone ointment is delivered in tubes with a plastic screw cap containing 30 grams.

Diprosone lotion is delivered in bottles with a plastic screw cap and plastic dropper containing 30 grams.

Holder of the marketing authorization and manufacturer

Registration holder:

Euro Registratie Collectief b.v.

Kempkens 2200

5465 PR Veghel

Repacker (see label on the outer packaging):

Brocef B.V., Maroastraat 43, 1060 LG Amsterdam

of

Stephar B.V., Kempkens 2200, 5465 PR Veghel

Manufacturer:

Organon Heist bv

Industriepark 30

B-2220 Heist-op-den-Berg

Belgium

Cenexi HSC
2 rue Louis Pasteur
F-14200 Hérouville St Clair
France

Registered under
RVG 129638//06650 Diprosone 0.5 mg/g cream (Spain)
RVG 17955//06650 Diprosone 0.5 mg/g cream (France)
RVG 123694//06864 Diprosone ointment, ointment 0.5 mg/g (Spain)
RVG 13546//08211 Diprosone 0.05% lotion, lotion 0.5 mg/g (France)

This medicine is marketed in the country of origin under the name:
France: Diprosone 0.05%, cream; Diprosone 0.05%, lotion
Spain: Diproderm 0.5 mg/g crema; Diproderm 0.5 mg/g pomada

This leaflet was last approved in November 2024 ((291024)).

BS000125 – mmjj / 070621-1122_DH&Z9D_A