

PACKAGE LEAFLET: INFORMATION FOR THE USER

Diprosone® Ointment 0.05% 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.

In this leaflet:

1. What Diprosone Ointment is and what it is used for
2. What you need to know before you use Diprosone Ointment
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1. WHAT DIPROSONE OINTMENT IS AND WHAT IT IS USED FOR

Diprosone Ointment contains the active ingredient betamethasone dipropionate.

Betamethasone dipropionate belongs to a group of medicines called topical corticosteroids which are used on the surface of the skin to reduce the redness and itchiness caused by certain skin problems.

Diprosone Ointment is used to treat skin problems, including eczema all types of dermatitis and psoriasis of the scalp, hands and feet in adults and children. Use in children under 12 only under medical supervision.

Eczema is a common skin disease, which causes the skin to become red and itchy. Dermatitis is inflammation of the skin. Psoriasis is a skin disease in which itchy, scaly, pink patches develop on the elbows, knees, scalp and other parts of the body.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE DIPROSONE OINTMENT

Do not use Diprosone Ointment

- if you are allergic to betamethasone dipropionate 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 around the mouth, genital itching, nappy rash, cold sores, chickenpox, shingles or other skin infections. Ask your doctor or pharmacist if you are not sure.

Warnings and precautions

Talk to your doctor or pharmacist before using diprosone ointment if you are concerned about any of the following:

- This medicine should not be used under nappies, bandages or plasters.
- Do not apply to the area around the eye as this may cause glaucoma
- Use of topical corticosteroids in children and adults can cause Cushing's syndrome (fatigue, muscle weakness, weight gain, high blood pressure, rounded face with a reddish complexion).

- HPA axis suppression in children and adults (fatigue, depression, anxiety, and suppressed immune system) can occur with large doses of corticosteroids, recovery is usually prompt on stopping treatment.
- If irritation develops, stop treatment
- Antifungal or antibacterial medicines should be used if a skin infection is present.
- Corticosteroids may cause cataract development.

Side effects that may happen with oral or injectable 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.

- Do not use in children under 12 without medical supervision and for more than one week
- High pressure in the skull (bulging fontanelle, headaches, swelling of the eyes) has been reported in children using corticosteroids.
- Children may be more likely to develop side effects.

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 DIPROSONE OINTMENT

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 Diprosone Ointment should be rubbed into the affected area of skin once to twice a day.

You should always follow these instructions when using Diprosone Ointment:

- Do not use the ointment on your face for more than one week.
- 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 diprosone ointment on any part of your child's body for more than one week. Do not put the ointment under your child's nappy, as this makes it easier for the active ingredient of the medicine to pass through the skin and possibly cause some unwanted effects.

If you use more Diprosone Ointment than you should

If you (or somebody else) accidentally swallows 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. 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 Diprosone Ointment

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 diprosone ointment

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, Diprosone Ointment 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 than you should, particularly on your face, it can cause redness, stinging, blistering, peeling, swelling, itching, burning, skin rash, dryness of the skin, inflammation of the hair follicles; excessive hair growth, reduced skin pigmentation; allergic skin reactions; dermatitis (skin inflammation); other skin infections, thinning of the skin and red marks.. This can happen more easily in infants and children. If you are worried by these or any other effects, you should tell your doctor or pharmacist.

If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

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

5. HOW TO STORE DIPROSONE OINTMENT

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

Do not use this medicine after the expiry date which is stated on the label and carton after 'Use by'. The expiry date refers to the last day of that month.

Do not store above 25°C.

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 Ointment contains**

- The active substance is betamethasone dipropionate 0.064% w/w (equivalent to 0.05% betamethasone).
- The other ingredients are liquid paraffin and white soft paraffin.

What Diprosone Ointment looks like and contents of the pack

Diprosone Ointment is a smooth, opaque (not clear) ointment. It is available in tubes containing 30g or 100g.

Marketing Authorisation Holder and Manufacturer

The holder of the Marketing Authorisation is:
Merck Sharp & Dohme Ireland (Human Health) Limited,

Red Oak North, South County Business Park,
Leopardstown, Dublin 18, Ireland.

The manufacturer is:
Schering-Plough Labo NV,
Heist-op-den Berg, Belgium.

This leaflet was last revised in September 2014