

PACKAGE LEAFLET: INFORMATION FOR THE USER

Diprosone® Ointment BETAMETHASONE DIPROPIONATE

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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Diprosone Ointment is and what it is used for
2. Before you use Diprosone Ointment
3. How to use Diprosone Ointment
4. Possible side effects
5. How to store Diprosone Ointment
6. Further information

1. WHAT DIPROSONE OINTMENT IS AND WHAT IT IS USED FOR

Diprosone Ointment contains the active ingredient 0.064% w/w 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.

In adults and children, Diprosone Ointment is used to treat skin problems, including eczema, all types of dermatitis and psoriasis of the scalp, hands and feet.

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. BEFORE YOU USE DIPROSONE OINTMENT

Do not use Diprosone Ointment

- if you are allergic (hypersensitive) to betamethasone dipropionate or any of the other ingredients of Diprosone Ointment. Refer to section 6 for a full list of ingredients.
- on any other skin problem as it could make it worse especially rosacea (a skin condition affecting the face), acne, dermatitis (skin inflammation) 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.

Pregnancy and breast-feeding

Tell your doctor if you are pregnant or breast-feeding, before you start using Diprosone Ointment.

3. HOW TO USE DIPROSONE OINTMENT

Always use Diprosone Ointment exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Usually for adults and children, a thin layer of Diprosone Ointment should be rubbed into the affected area of skin twice a day.

You should always follow these instructions when using Diprosone Ointment:

- Do not use the ointment on your face for more than 5 days.
- If Diprosone Ointment is used in children, it should not be used on any part of their body for more than 5 days.

- 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.
- 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.

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. 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.

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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Diprosone Ointment can cause side effects, although not everybody gets them.

Most people find that when the lotion is used correctly, it does not cause any problems. However, if you use the lotion more than you should, particularly on your face, it can cause redness, stinging, blistering, peeling, swelling, itching, burning, skin rash, dryness of the skin, in 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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE DIPROSONE OINTMENT

Do not store the ointment above 25°C.
Keep it out of the reach and sight of children.

Do not use the ointment after the date which is stamped on the pack.

6. FURTHER INFORMATION

What Diprosone Ointment contains

- The active substance is betamethasone dipropionate Ph.Eur 0.064% w/w (equivalent to 0.05% w/w 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 Limited,
Hertford Road, Hoddesdon,
Hertfordshire, EN11 9BU, UK.

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

This leaflet was last approved in January 2011.