

Package leaflet: Information for the user

Diprosone® 0.05 % w/w Ointment betamethasone (as dipropionate 0.064 %)

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 Ointment is and what it is used for
2. What you need to know before you use Diprosone Ointment
3. How to use Diprosone Ointment
4. Possible side effects
5. How to store Diprosone Ointment
6. Contents of the pack and other information

1. What Diprosone Ointment is and what it is used for

Diprosone Ointment contains the active ingredient 0.064% w/w betamethasone dipropionate (equivalent to 0.05% w/w betamethasone).

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. Corticosteroid creams, ointments and other topical preparations come in four different potencies or strengths. These are known as mild, moderately potent, potent or very potent. Healthcare professionals will usually refer to topical corticosteroid potency rather than strength. A potent or strong corticosteroid has a much stronger effect than a mild corticosteroid when using the same amount. The percentage of active ingredient that is sometimes included on product packaging does not indicate potency. Diprosone is classed as a strong corticosteroid. Your healthcare professional will prescribe or advise a steroid of the appropriate potency for your condition.

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. What you need to know before you use Diprosone Ointment

Do not use Diprosone Ointment

If you have:

- an allergy to betamethasone dipropionate or any of the other ingredients in this medicine (listed in section 6).
- 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.

Warnings and precautions

If you have psoriasis, your doctor may want to review your treatment regularly. Contact your doctor if your psoriasis gets worse or you get raised bumps filled with pus under your skin.

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

This medicine should not be used under bandages or plasters.

Side effects that may happen with oral or injectable corticosteroids may also occur with corticosteroids used on the skin, especially in infants and children.

If you use more than the correct amount of ointment and/or use it for longer than is recommended, it can affect the levels of certain hormones in the body, particularly in infants and children.

In adults the changes in hormone levels may lead rarely to puffiness or rounding of the face, weakness, tiredness, and dizziness when standing or sitting down.

Do not smoke or go near naked flames – risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

If there is a worsening of your condition during use consult your prescriber – you may be experiencing an allergic reaction, have an infection or your condition requires a different treatment.

If you experience a recurrence of your condition shortly after stopping treatment, within 2 weeks, do not restart using the ointment without consulting your prescriber unless your prescriber has previously advised you to do so. If your condition has resolved and on recurrence the redness extends beyond the initial treatment area and you experience a burning sensation, please seek medical advice before restarting treatment.

Children

If you use more than the correct amount of ointment and/or use it for longer than is recommended, it can affect your child's hormones. Rarely this may lead to:

- Delayed growth and development
- Puffiness or rounding of the face
- A build-up of pressure around the brain which can produce
 - a bulging of the fontanelle (the soft spot in the top of the skull) in infants
 - a constant thumping headache
 - blurred vision or other visual disturbances

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.

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.

3. How to use Diprosone Ointment

Always use Diprosone Ointment 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 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.
- Do not use a large amount of ointment on large areas of the body, open wounds or areas of the body where joints bend 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 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.

If you use more Diprosone Ointment than you should

If you (or somebody else) accidentally swallow 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.

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, red marks and blurred vision.

Steroid withdrawal reaction:

If used over prolonged periods a withdrawal reaction, which might appear to be different from the previous condition, may occur in some patients during treatment or within days to weeks after stopping treatment, with some or all of the following features: redness of the skin which can extend beyond the initial area treated, a burning or stinging sensation, intense itching, peeling of the skin, oozing open sores.

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.

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. You can also report side effects directly via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. 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 'EXP'. The expiry date refers to the last day of the month.

Do not store the ointment 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. Each gram contains 0.64 mg of betamethasone dipropionate (equivalent to 0.5 mg 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. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The holder of the Marketing Authorisation is:
Organon Pharma (UK) Limited,
Shotton Lane, Cramlington, United Kingdom,
NE23 3JU.

The manufacturer is:
Organon Heist bv
Industriepark 30
2220 Heist-op-den-Berg
Belgium

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