Package leaflet: Information for the user

DiproSone® 0.05 % w/w Cream
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 cream is and what it is used for

Diprosone cream 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. 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 cream is used to treat skin problems, including eczema, and 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 cream

Do not use Diprosone cream
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 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 cream 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 cream 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 cream 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

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.

Diprosone cream contains chlorocresol and cetostearyl alcohol
Diprosone cream contains chlorocresol, which may cause allergic reactions and cetostearyl alcohol, which may cause local skin reactions (e.g. contact dermatitis).

3. How to use Diprosone cream

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 cream should be rubbed into the affected area of skin twice a day.

You should always follow these instructions when using Diprosone cream:
- Do not use the cream on your face for more than 5 days.
- Do not use a large amount of cream 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 cream in your eyes.

Use in children
Use as stated above. Do not use Diprosone cream on any part of your child's body for more than 5 days. Do not put the cream 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 cream than you should
If you (or somebody else) accidentally swallows the cream, it should not cause any problems. However, if you are worried, you should see your doctor.

If you use the cream 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 cream 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 cream
If you forget to use your cream at the right time, use it as soon as you remember, then carry on as before.

If you stop using Diprosone cream
If you have been using the cream for a long time and your skin problem seems to have got better, you should not suddenly stop using the cream. 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 cream 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, this medicine can cause side effects, although not everybody gets them.

Most people find that when the cream is used correctly, it does not cause any problems. However, if you use the cream 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 reactions, dermatitis (skin inflammation), other skin infections, thinning of the skin, red marks and blurred vision. This can happen more easily in infants and children. If you are worried by these or any other side effects, you should tell your doctor or pharmacist.

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.

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 cream

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 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 cream 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 chlorocresol, sodium dihydrogen phosphate dihydrate, phosphoric acid, white soft paraffin, liquid paraffin, cetomacrogol 1000, cetostearyl alcohol, sodium hydroxide and purified water.

What Diprosone cream looks like and contents of the pack
Diprosone cream is a smooth, white cream. It is available in tubes containing 5 g, 30 g or 100 g. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
The holder of the Marketing Authorisation is:
Organon Pharma (UK) Limited,
The Hewett Building, 14 Hewett Street, London EC2A 3NP, United Kingdom.

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

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