SCHEDULING STATUS

S4

DIPROSONE® Cream

DIPROSONE® Ointment

Betamethasone (as dipropionate) 0,5 mg

Read all of this leaflet carefully before you start taking DIPROSONE

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- DIPROSONE has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What DIPROSONE is and what it is used for

- DIPROSONE contains a cortisone-type medicine which is used on the skin to reduce redness and itchiness caused by certain skin problems.
- DIPROSONE is used to treat skin problems, including eczema, dermatoses, and psoriasis.
- Eczema is a common skin disease, which causes the skin to become red and itchy. Dermatoses is a non-inflammatory skin disorder, which may cause thickening and

hardening 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

Do not use DIPROSONE:

- if you are allergic (hypersensitive) to betamethasone or any of the other ingredients of DIPROSONE.
- if you are under treatment for herpes infections, vaccine reactions or chicken pox (varicella).

Warnings and precautions

Take special care with **DIPROSONE**

- DIPROSONE is for use only on the skin. Avoid contact with the eyes. Use with particular caution on facial skin and only for short periods.
- Do not use DIPROSONE more often or for a longer time than your doctor recommends.
- Do not use DIPROSONE if your skin condition worsens. Check with your doctor if your skin condition worsens.
- Do not use DIPROSONE on large areas of the body, as this will increase the amount absorbed.
- Do not use DIPROSONE under bandages and plasters or if skin is damaged.
- Do not use DIPROSONE in any skin crease areas.
- Children and adolescents who must use DIPROSONE should be followed closely by their doctor, since DIPROSONE is absorbed through the skin and can affect growth or cause other unwanted effects.
- DIPROSONE should not be used in nappy areas and ideally should not be used in infants and young children at all.
- If you experience visual disturbances including blurred vision.

If there is a worsening of your condition during use consult your doctor – 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 or ointment without consulting your doctor unless your doctor 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.

Other medicines and DIPROSONE

Always tell your healthcare provider if you are taking any other medicine (this includes all complementary or traditional medicines).

Pregnancy and Breastfeeding

DIPROSONE should not be used in pregnancy and in mothers who are breastfeeding.

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using this medicine.

Driving and using machinery

It is not always possible to predict to what extent DIPROSONE may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which DIPROSONE affects them.

3. How to use DIPROSONE

- Do not share medicines prescribed for you with any other person.
- Always use DIPROSONE exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

- Apply a thin film of DIPROSONE to cover the affected area and massage in gently, usually twice a day (morning and night) or as directed by your doctor. Mild cases may respond to once-a-day application.

Your doctor will tell you how long your treatment with DIPROSONE will last. If you have an impression that the effect of DIPROSONE is too strong or too weak, talk to your doctor or pharmacist.

If you use more DIPROSONE than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison control centre.

If you forget to use DIPROSONE

If you forget to use your cream or ointment at the right time, use it again at your next dose as usual.

Do not use a double dose to make up for forgotten individual applications.

If you stop using DIPROSONE

If you stop using DIPROSONE, you will lose the effects of this medicine. You should not stop using this medicine, unless your doctor tells you as your symptoms may return.

4. Possible side effects

DIPROSONE can have side effects.

Should your general health worsen or if you experience any untoward effects while using DIPROSONE, please consult your healthcare provider for advice.

The following have been reported and the frequencies are unknown: Burning, itching, irritated or dry skin, irritation or redness of the face, increased hair growth, acne, change in skin colour, thinning of skin with easy bruising, blurred vision, stretch marks or other signs of irritation not present before use of DIPROSONE.

Steroid withdrawal reaction:

If used continuously for prolonged periods a withdrawal reaction may occur on 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.

Not all side effects reported for DIPROSONE are included in this leaflet.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get 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 to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of DIPROSONE.

5. How to store DIPROSONE

Store at or below 25°C.

Store all medicines out of the reach of children.

Do not use after the expiry date stated on the tube.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What DIPROSONE contains

The active substance is 0,5 mg betamethasone (as dipropionate).

DIPROSONE Cream: The other ingredients are: Ceteth-20, cetostearyl alcohol, liquid paraffin, monobasic sodium phosphate, phosphoric acid, sodium hydroxide, white soft paraffin and purified water.

Preservative: Chlorocresol 0,1 % *m/m*

DIPROSONE Ointment: The other ingredients are: liquid paraffin and white soft paraffin.

What DIPROSONE looks like and contents of the pack

DIPROSONE Cream: A smooth, white cream.

DIPROSONE Ointment: A smooth, white ointment.

DIPROSONE Cream and Ointment are packed in tubes of 20 g and 30 g, in cartons.

Holder of Certificate of Registration

Organon South Africa (Pty) Ltd

Spaces, 1st Floor

22 Magwa Crescent, Gateway West

Waterfall City, Midrand, 2090

South Africa

This leaflet was last revised on

21 June 2024

Registration numbers

DIPROSONE Cream: F/13.4.1/17

DIPROSONE Ointment: F/13.4.1/18

© 2024 Organon group of companies. All rights reserved.

S-CCDS-MK1460-DPS-MTL-082017; RCN100002505.