

## SCHEDULING STATUS

S4

### DIPROSALIC® Ointment

Betamethasone (as dipropionate) 0,5 mg and salicylic acid 30 mg

#### Read all of this leaflet carefully before you start using DIPROSALIC Ointment

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

#### 1. What DIPROSALIC Ointment is and what it is used for

DIPROSALIC Ointment contains two active ingredients, betamethasone and salicylic acid.

Betamethasone is a cortisone-type medicine put on the surface of the skin to reduce redness and itchiness caused by certain skin problems. Salicylic acid softens the top layer of scales on the surface of the skin which are caused by your skin problem. This allows the betamethasone to reach the diseased skin underneath to help heal it.

DIPROSALIC Ointment is used to treat skin conditions where the outer surface of the skin is covered by a layer of scales (psoriasis). Your ointment will remove the layer of scales and reduce the redness and itchiness caused by your skin problem.

## **2. What you need to know before you use DIPROSALIC Ointment**

### **Do not use DIPROSALIC Ointment:**

- If you are allergic (hypersensitive) to betamethasone dipropionate and salicylic acid or any of the other ingredients of DIPROSALIC Ointment.
- If you are under the treatment of herpes infections, vaccine reactions or chicken pox (varicella).

### **Warnings and precautions**

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

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 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 DIPROSALIC Ointment**

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

#### **Pregnancy and 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.

The use of DIPROSALIC Ointment is not recommended for mothers who are breastfeeding.

#### **Driving and using machinery**

It is not always possible to predict to what extent DIPROSALIC Ointment 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 DIPROSALIC Ointment affects them.

### **3. How to use DIPROSALIC Ointment**

Do not share medicines prescribed for you with any other person.

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

Apply a thin layer of DIPROSALIC Ointment to the affected skin areas and massage gently and thoroughly into the skin, usually twice daily (in the morning and at night) or as directed by your doctor.

Do not bandage or otherwise wrap the skin being treated unless directed to do so by your doctor. Do not use tight-fitting diapers or plastic pants on a child being treated with DIPROSALIC Ointment unless directed to do so by your doctor. Do not apply DIPROSALIC Ointment to deep skin wounds, puncture wounds, serious burns, or raw areas.

If you have the impression that the effect of DIPROSALIC Ointment is too strong or too weak, talk to your doctor or pharmacist.

Your doctor will tell you how long your treatment with DIPROSALIC Ointment will last.

**If you use more DIPROSALIC Ointment than you should**

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

**If you forget to use DIPROSALIC Ointment**

If you forget to use your DIPROSALIC Ointment at the right time, use it as soon as you remember, then carry on as before. Do not use a double dose to make up for forgotten individual doses.

**If you stop using DIPROSALIC Ointment**

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

#### **4. Possible side effects**

DIPROSALIC Ointment can have side effects.

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

The following have been reported and the frequencies are unknown:

- Redness, stinging, blistering, peeling, swelling, itching, burning, skin rash, dryness of the skin.
- Inflammation of the hair follicles, excessive hair growth.
- Darkening of the skin, allergic skin reactions, dermatitis around the mouth, other skin infections, thinning of the skin and red marks.
- Blurred vision.

#### **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 DIPROSALIC Ointment 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 DIPROSALIC Ointment.

## 5. How to store DIPROSALIC OINTMENT

Store at or below 25°C.

Protect from light.

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 DIPROSALIC Ointment contains

**The active substances are:** Each gram of DIPROSALIC Ointment contains 0,5 mg of betamethasone (as dipropionate) and 30 mg of salicylic acid.

**The other ingredients are:** Liquid paraffin and white soft paraffin.

### What DIPROSALIC Ointment looks like and contents of the pack

DIPROSALIC Ointment is white, greasy ointment.

DIPROSALIC Ointment is packed in tubes of 20 g.

### Holder of Certificate of Registration

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**This leaflet was last revised on**

21 June 2024

**Registration numbers**

H/13.4.1/32

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S-CCDS-MK-0887-MTL-082017; RCN100002507.