

## Package leaflet: Information for the user

### Diprosalic® 0.05% w/w / 3% w/w Ointment

Betamethasone dipropionate/salicylic acid

**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.

#### **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 dipropionate and salicylic acid. Betamethasone dipropionate is one of a group of medicines called topical corticosteroids. It is classified as a “potent corticosteroid”. These medicines are put on the surface of the skin to reduce the 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 dipropionate to reach the diseased skin underneath to help heal it.

In adults and children, diprosalic ointment is used to treat skin conditions where the outer surface of the skin is covered by a layer of scales. 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 to betamethasone dipropionate, salicylic acid or any of the other ingredients in this medicine (listed in section 6).
- 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 or other skin conditions.

##### **Warnings and precautions**

Talk to your doctor or pharmacist before using diprosalic ointment.

This medicine should not be used under bandages or plasters.

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

##### **Children**

If the ointment is used more often than it should, or more than prescribed, it can affect some of your child's hormones. This may affect their growth and development.

### **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.

### **3. How to use diprosalic ointment**

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 diprosalic ointment should be gently rubbed into the affected area of skin twice a day.

You should always follow these instructions when using diprosalic 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 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 this 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 ingredients of the medicine to pass through the skin and possibly cause some unwanted effects.

#### **If you use more diprosalic 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. It also may cause you to feel and/or be sick and to hear ringing in your ears. 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 or pharmacist.

#### **If you forget to use diprosalic 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 diprosalic 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, this medicine 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 often than you should, it can cause the following:

- Thinning of the skin, stinging, blistering, peeling, swelling, itching, burning, skin rash, dryness of the skin and you may notice red marks. This can happen more easily in infants and children.
- Inflammation of the hair follicles, excessive hair growth, reduced skin pigmentation and allergic skin reactions.
- Dermatitis (skin inflammation), a condition brought on by the skin reacting to outside agent e.g. detergents, causing the skin to become red and itchy.

**If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.**

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

**United Kingdom:** Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

**Ireland:** Pharmacovigilance Section, Irish Medicines Board, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: [www.imb.ie](http://www.imb.ie), e-mail: [imbpharmacovigilance@imb.ie](mailto:imbpharmacovigilance@imb.ie)

**Malta:** ADR Reporting, The Medicines Authority, Post-Licensing Directorate, 203 Level 3, Rue D'Argens, GŻR-1368 Gżira Website: [www.medicinesauthority.gov.mt](http://www.medicinesauthority.gov.mt), e-mail: [postlicensing.medicinesauthority@gov.mt](mailto:postlicensing.medicinesauthority@gov.mt)

## **5. How to store diprosalic 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 tube 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 diprosalic ointment contains**

- The active substances are betamethasone dipropionate 0.064 % w/w (equivalent to 0.05 % w/w betamethasone) and salicylic acid 3.0 % w/w.
- The other ingredients are liquid paraffin and white soft paraffin.

### **What Diprosalic Ointment looks like and contents of the pack**

Diprosalic ointment is a smooth, off-white ointment. It is available in tubes containing 30 g or 100 g.

### **Marketing Authorisation Holder and Manufacturer**

**The Marketing Authorisation Holder** in the UK and Malta is Merck Sharp & Dohme Ltd, Hertford Road, Hoddesdon, Hertfordshire, EN11 9BU, UK.

**The Marketing Authorisation Holder** in Ireland is Merck Sharp & Dohme Ireland (Human Health) Ltd, Red Oak North, South County Business Park, Leopardstown, Dublin 18, Ireland.

### **The manufacturer is:**

Schering-Plough Labo NV,  
Heist-op-den Berg, Belgium.

**This leaflet was last approved in December 2013**