Diprosalic® Ointment

(betamethasone dipropionate and salicylic acid)

Patient Information Leaflet

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 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. These medicines are put 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. Diprosalic is classed as a strong corticosteroid. Your healthcare professional will prescribe or advise a steroid of the appropriate potency for your condition.

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 have:

- an allergy to betamethasone dipropionate, salicylic acid 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 or other skin conditions.

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 immediately 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 inhaled or oral 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

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 or inside your nose or mouth.

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.
- 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.

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 Diprosalic Ointment

- Do not store above 25°C.
- Keep all medicines out of the sight and reach of children.
- If your doctor tells you to stop taking the Ointment, please take them back to the pharmacist for safe disposal. Only keep them if your doctor tells you to.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6) Contents of the pack and other information

What Diprosalic Ointment contains:
It contains the active ingredients, Betamethasone (as the Dipropionate Ester) 0.05% and 3% Salicylic Acid.

Diprosalic Ointment also contains: liquid paraffin and white soft paraffin.

What Diprosalic Ointment looks like and contents of the pack
Diprosalic Ointment is a smooth, white, preservative-free ointment.

Diprosalic Ointment is available as 30g tubes of sterile ointment.

PL 46420/0176 **POM**

Who makes and repackages your medicine?
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For any information about this medicine or to request a copy of this leaflet in Braille, large print or audio, please call the PL holder: Suerte Pharma Limited on 020 8839 3000.