

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS REGULATIONS
(PREPARATIONS) 1986**

This medicine can be sold under doctor's prescription only

DIPROSALIC[®] OINTMENT

Active ingredients:

Each gram contains:

Betamethasone Dipropionate 0.64 mg (equivalent to 0.5 mg Betamethasone)

Salicylic Acid 30 mg

For a list of inactive ingredients see section 6.1 "What **Diprosalic Ointment** contains?"

Read all of this leaflet carefully before you start using this medicine.

- This leaflet contains concise information about **Diprosalic Ointment**. If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their ailment seems similar to yours.

1. WHAT IS DIPROSALIC OINTMENT INTENDED FOR?

Diprosalic Ointment provides anti inflammatory, antipruritic, anti allergic and keratolytic activity in the topical management of subacute dermatoses responsive to corticosteroid therapy.

THERAPEUTIC GROUP: 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.

2. BEFORE USING THE MEDICINE

2.1 Do not use Diprosalic Ointment:

- if you are sensitive (allergic) to betamethasone dipropionate, salicylic acid or any of the other ingredients in this medicine (listed in section 6).
- if you have 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.

2.2 Special warnings concerning use of Diprosalic Ointment

Talk to your doctor or pharmacist before using **Diprosalic Ointment**.

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 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.

2.3 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

2.4 Drug interactions

If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, you should inform the doctor or pharmacist.

2.5 Pregnancy and breast-feeding

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 about the dosage and about how to use this medicine.

The dosage and treatment regimen will be determined by the doctor only.

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.

Do not exceed the recommended dose.

If you use more Diprosalic Ointment than you should

If you have taken an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you.

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 vomiting and/or nausea 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 the 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 that, 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.

Complete the full course of treatment as instructed by the doctor.

Even if there is an improvement in your health, do not discontinue use of this medicine before consulting your doctor.

Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them. If you have further questions on the use of the medicine, consult with a doctor or a pharmacist.

4. SIDE EFFECTS

Like all medicines, **Diprosalic Ointment** can cause side effects, in some of the users.

Do not be alarmed by reading the list of side effects, you may not suffer from any of 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:

- 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.

If a side effect appears, if any of the side effects gets serious or if you notice a side effect not mentioned in this leaflet, consult your doctor.

Side effects can be reported to the Ministry of Health by using the link "Adverse Drug Reactions Report" at the home page of the Ministry of Health's web site (www.health.gov.il) which refers to the online side effects reporting form, or by using the link: <https://sideeffects.health.gov.il>

5. HOW TO STORE DIPROSALIC OINTMENT?

- Avoid Poisoning! This medicine, as all other medicines, must be stored in a safe place out of the reach and sight of children and/or infants, in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use this medicine after the expiry date (exp. date) which is stated on pack. The expiry date refers to the last day of the indicated month.
- Storage conditions: Store not above 25°C.
- Do not use beyond 3 months from first opening.
- 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. FURTHER INFORMATION

6.1 What Diprosalic Ointment contains?

- The active ingredients are betamethasone dipropionate and salicylic acid. Each gram contains 0.64 mg of betamethasone dipropionate (equivalent to 0.5 mg betamethasone) and 30 mg of salicylic acid.
- In addition to the active ingredients the medicine also contains:
White petrolatum, mineral oil.

6.2 What Diprosalic Ointment looks like and contents of the pack

Diprosalic Ointment is a smooth, off-white ointment. It is available in tubes containing 15 gram or 30 gram. Not all pack sizes may be marketed.

6.3 License Holder and address:

Organon Pharma Israel Ltd., 1 Atir Yeda, Kfar Saba

6.4 Manufacturer: Organon LLC, NJ USA

Revised in December 2024.

Drug registration no. listed in the official registry of the Ministry of Health:

135.51.24242