

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 THE MEDICINE USED 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. 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.

2. BEFORE USING THE MEDICINE

2.1 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.

2.2 Special warnings concerning use of Diprosalic Ointment

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.

Contact your doctor if you experience blurred vision or other visual disturbances.

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.

2.3 Children

If **Diprosalic 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.

2.4 Taking other medicines

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.

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.

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 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, nausea and ringing in the 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 suffer from redness stinging and burning of the scalp. 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 any further questions on the use of this medicine, ask your doctor or 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.

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 reactions.
- Dermatitis (skin inflammation), a condition brought on by the skin reacting to outside agents, causing the skin to become red and itchy.
- Blurred vision.

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.
- In addition to the active ingredients the medicine also contains inactive ingredients: Mineral oil, white petrolatum.

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.

6.3 License Holder:

Merck Sharp & Dohme (Israel-1996) Company Ltd., P.O.Box 7121, Petah-Tikva 49170.

6.4 Manufacturer:

Schering-Plough Labo N.V., Heist-op-den-berg, Belgium.

This Leaflet was checked and approved by the Ministry of Health in December 2018 and updated according to the guidelines of the Ministry of Health in August 2019.

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

135-51-24242.