

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION



DIPROSALIC®

Betamethasone Dipropionate and Salicylic Acid Lotion
Betamethasone Dipropionate and Salicylic Acid Ointment

Read this carefully before you start taking **DIPROSALIC®** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **DIPROSALIC®**.

What is DIPROSALIC® used for?

- **DIPROSALIC®** is used to treat persistent skin problems where the top of the skin is covered by a layer of scales. **DIPROSALIC®** will remove the layer of scales and reduce the swelling, redness and itchiness caused by your skin problem.

How does DIPROSALIC® work?

DIPROSALIC is a combination of 2 drugs, betamethasone dipropionate and salicylic acid.

- salicylic acid will work on the surface of your skin by softening the top layer of the scales. This allows the second drug to reach underneath the infected skin to help heal it.
- betamethasone dipropionate will reduce the swelling, redness and itchiness off your skin.

What are the ingredients in DIPROSALIC®?

Medicinal ingredients: betamethasone dipropionate, salicylic acid.

Non-medicinal ingredients:

Lotion: edetate disodium, hydroxypropylmethylcellulose, isopropyl alcohol, water and sodium hydroxide.

Ointment: mineral oil and white petrolatum.

DIPROSALIC® comes in the following dosage forms:

Lotion: 60 mL Plastic squeeze bottles

Ointment: 50 g Tubes

Do not use DIPROSALIC® if you:

- are allergic to betamethasone dipropionate, salicylic acid, or any of the other ingredients of **DIPROSALIC®**.
- have any infections like small pox (vaccinia), chicken pox (varicella), cold sores or genital herpes (herpes simplex virus), fungal infections or a skin infection (tuberculosis of the skin).

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take DIPROSALIC®. Talk about any health conditions or problems you may have, including if you:

- are pregnant or planning on becoming pregnant. It is not known if DIPROSALIC® can harm your unborn baby. Your healthcare professional will decide whether giving you DIPROSALIC® outweighs the potential risk to the unborn baby.
- are breastfeeding or planning to breastfeed. It is not known whether DIPROSALIC® can pass into your breastmilk. Your healthcare professional will decide whether to stop breastfeeding or stop the use of DIPROSALIC®.
- have any infections.
- have diseases of your skin that are caused by poor blood flow. An example is stasis dermatitis.

Other warnings you should know about:

- Avoid getting DIPROSALIC® in your genital area.
- Avoid getting the ointment inside your eyes, mouth, ears and nose.
- In children, limit the use of DIPROSALIC® to the minimum required amount needed. Long-term use of this medicine may affect your child's hormones. This may affect your child's growth and development.

Eyes:

- Avoid using DIPROSALIC® in or near your eyes.
- Talk to your healthcare professional if you develop:
 - Blurred vision
 - Other eyesight problems

Skin:

- Do not put any bandages or plasters over the medicine.
- Do not use excessive amounts of DIPROSALIC® on large areas of the body.
- Talk to your healthcare professional if you develop:
 - Irritation
 - Sensitive skin
 - Extremely dry skin
 - Unwanted scaling of your skin
 - Flaking of your skin
 - Stretch marks (striae)

These symptoms may happen when you are using a corticosteroid for a long time. You may need to stop your treatment.

Use of DIPROSALIC® on large infected areas of the skin may:

- Reduce the creation of hormones
- Cause swelling of face (moon facies)
- Reduce growth

Driving and using machines: Give yourself time after taking DIPROSALIC® to see how you feel before driving a vehicle or using machinery.

Tell your healthcare professional about all the medicines you take, including any drugs,

vitamins, minerals, natural supplements or alternative medicines.

How to take DIPROSALIC®:

Lotion: A thin film should be applied twice a day to the affected areas of your scalp. Apply the lotion to cover the entire affected area.

Ointment: A thin film should be applied twice a day, in the morning and night, to the affected area. The ointment should be massaged gently and thoroughly into the skin. The ointment should cover the entire affected area.

If you do not notice an improvement within a few days to a week, stop the use of DIPROSALIC® and you should consult your healthcare professional.

Overdose:

If you think you have taken too much DIPROSALIC®, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed dose

If you miss an application of this medication, resume treatment with the next scheduled dose. Do not apply more than once at the same time.

What are possible side effects from using DIPROSALIC®?

These are not all the possible side effects you may feel when taking DIPROSALIC®. If you experience any side effects not listed here, contact your healthcare professional.

Local skin problems have been reported when applying topical steroids. The following have been reported:

- Burning
- Itching
- Irritation
- Dryness
- Swelling of the hair follicles
- Excessive hair growth
- Acne outbreaks that result in redness and blushing
- Patches of lighter skin tone
- Skin rash around the mouth
- Red, itchy rash caused by
 - direct contact with a substance or
 - an allergy reaction to the substance

Plasters and bandages should not be used over DIPROSALIC®. The following may occur more often if plasters or bandages are used:

- Softening and breaking down of skin
- A new infection after treatment (secondary infection)
- Thinning of the skin (skin atrophy)
- Stretch marks

- Heat rash

Salicylic acid, an ingredient found in DIPROSALIC[®], may cause the following:

- local reddening of the skin
- skin peeling
- itching
- feeling a sharp stinging pain

The continual use of products containing salicylic acid to the skin may cause eczema. An allergy to salicylic acid may occur.

Blurry vision has also been reported with the use of topical corticosteroids.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store between 15°C and 30°C. Protect from light.

Keep out of reach and sight of children.

If you want more information about DIPROSALIC[®]:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada.html>); the Organon Canada website www.organon.ca, or by calling Organon Canada at 1-844-820-5468.

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