

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrDIPROSALIC®

Betamethasone Dipropionate and Salicylic Acid Ointment

This Patient Medication Information is written for the person who will be taking **DIPROSALIC**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **DIPROSALIC**, talk to a healthcare professional.

What DIPROSALIC is used for:

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

How DIPROSALIC works:

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.

The ingredients in DIPROSALIC are:

Medicinal ingredient(s): betamethasone dipropionate, salicylic acid.

Non-medicinal ingredients: mineral oil and white petrolatum.

DIPROSALIC comes in the following dosage form:

Ointment: 0.05% Betamethasone Dipropionate and 3% Salicylic Acid, supplied in 50g tubes.

Do not use DIPROSALIC if:

- you are allergic to betamethasone dipropionate, salicylic acid, or any of the other ingredients of DIPROSALIC.
- you 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:

- **Slowed growth in children:** In children, the use of DIPROSALIC should be limited to the minimum amount needed. Long-term use of this medicine may affect your child's hormones. This may affect your child's growth and development.
- **Eyes:**
 - DIPROSALIC is a topical steroid. Topical steroids may cause eye problems.
 - Talk to your healthcare professional if you develop:
 - Blurred vision
 - Other eyesight problems
- **Skin:**
 - Do not put any bandages or plasters over the medicine. Covering the area may increase the amount of medicine absorbed through your skin.
 - 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.
 - Do not use excessive amounts of DIPROSALIC on large areas of the body.
 - 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 using 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:

- Use DIPROSALIC exactly as your healthcare professional tells you. Talk to your healthcare professional if you are not sure.

- DIPROSALIC is only for use on skin (topical use).
- Avoid getting the ointment:
 - inside or near your eyes
 - in your mouth, ears or nose
 - in your genital area.

Usual dose:

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, or a person you are caring for, have used too much or accidentally swallowed DIPROSALIC, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or 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.

Possible side effects from using DIPROSALIC:

These are not all the possible side effects you may have when using DIPROSALIC. If you experience any side effects not listed here, tell your healthcare professional.

- Skin effects:

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

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

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

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

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

- feeling a sharp stinging pain
 - itching
 - local reddening of the skin
 - skin peeling
 - eczema with the continual use of products containing salicylic acid. An allergy to salicylic acid may occur.
- Eye effects:
 - Blurry vision

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell 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 (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare 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 the Patient Medication Information by visiting the Health Canada Drug Product Database website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.organon.ca; or by calling 1-844-820-5468.

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