

# DIPROSALIC<sup>®</sup> OINTMENT

Betamethasone dipropionate/salicylic acid (0.5 mg/30 mg)

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## What Diprosalic ointment is used for

Diprosalic ointment is used to relieve the inflammatory symptoms caused by skin thickening and certain skin problems that respond to corticosteroids including psoriasis, dermatitis, eczema, ichthyosis and lichen planus.

Psoriasis is a skin disease in which itchy, scaly, red patches develop on the elbows, knees, scalp and other parts of the body. Eczema is a common itchy skin condition with redness, swelling, oozing of fluid, crusting which may lead to scaling. Dermatitis is inflammation of the skin. Ichthyosis is a skin disease that is characterized by dry, scaling skin that may be thickened

## How Diprosalic ointment works

Diprosalic ointment contains active ingredients of betamethasone dipropionate and salicylic acid.

Betamethasone dipropionate belongs to a group of medicines called topical corticosteroids which are used 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. Salicylic acid also stops bacteria and fungi from reproducing.

## Before you use Diprosalic ointment

### - When you must not use it

### Do not use Diprosalic ointment

- if you are allergic (hypersensitive) to betamethasone dipropionate, salicylic acid, or any of the other ingredients in this medicine (listed in "Ingredients").
- Before you start to use it
  - Talk to your doctor or pharmacist before using Diprosalic ointment.
  - This medicine should not be used under bandages or plasters unless you are told to do so by your doctor.

## Pregnancy and breastfeeding

- Medicines of this class should not be used on pregnant women in large amount or for prolonged periods of time.
- Diprosalic ointment is not recommended for nursing woman
- If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

## Children

Do not put the ointment under your child's diaper as this makes it easier for the active ingredient of the

medicine to pass through the skin and possibly cause some unwanted effects, unless you are told to do so by your doctor.

### - Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

## How to use Diprosalic ointment

### - How much to use

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Apply a thin film of Diprosalic ointment to cover completely the affected area twice daily.

### - When to use it

Apply Diprosalic ointment twice daily, in the morning and at night. If your skin problem improves you should talk to your doctor, it may be possible for you to apply the ointment less frequently.

### - How long to use it

Do not use Diprosalic ointment for long periods of time unless told by your doctor.

### - If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Use the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

### - If you used too much (overdose)

It 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

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too often and/or for a long time, you should tell your doctor or pharmacist.

## While you are using it

### - Things you must do

- Tell your doctor or pharmacist if you have any other skin problem.
- Use your medicine exactly as your doctor has told you.
- Tell your doctor immediately if you become pregnant while using this medicine.
- If your skin become dry, irritated or sensitive after using Diprosalic ointment, you should stop using it and tell your doctor.
- If you think that you have developed a skin infection while using Diprosalic ointment you should tell your doctor.

### - Things you must not do

- Do not give Diprosalic ointment to anyone else, even if they have the same symptoms or condition as you.
- Do not use Diprosalic ointment more often than you should, on large areas of the body, for a long period of time, under bandages, plasters, or diapers, or more than prescribed, as that may increase the chance of side effects, unless you are told to do so by your doctor.
- Avoid getting the ointment into your eyes, or mucous membranes.

### - Things to be careful of

#### Use in children

Children have greater absorption due to a large skin surface area to body weight ratio. Adrenal gland suppression, Cushing's syndrome, growth retardation, delayed weight

gain, and increased pressure in the skull have been reported in children receiving topical corticosteroids.

Manifestations of adrenal gland suppression in children include low blood cortisol levels and absence of response to certain hormone stimulation. Manifestations of intracranial hypertension include headaches and swelling of eye nerve.

If the ointment is used more often than it should, on large areas of the body, for a long period of time, or more than prescribed, it can affect some of your child's hormones. This may affect their growth and development.

## Side effects

Like all medicines, Diprosalic ointment can cause side effects, although not everybody gets them.

Side effects that have been reported with the use of topical corticosteroid include:

- burning
- itching
- irritation of the skin
- dryness of the skin
- inflammation of hair follicles
- excessive hair growth
- acne
- reduced pigmentation of the skin
- perioral dermatitis (small red bumps around the mouth)
- allergic skin reactions

Side effects that are commonly reported with the use of Diprosalic ointment under bandage or plaster include:

- softening and breakdown of the skin
- secondary infection of the skin

- thinning of the skin
- stretch marks
- heat rash

Salicylic acid may also cause dermatitis (skin inflammation).

Tell your doctor if you get any side effects. Side effects that may happen with inhaled or oral corticosteroids may also occur with corticosteroids used on the skin, especially in infants and children.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website: [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers → Reporting)

## Storage and Disposal of Diprosalic ointment

### - Storage

- Keep out of reach and sight of children.
- Store below 30°C.
- Protect from light.

### - Disposal

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.

## Product Description

### - What it looks like

Smooth, uniform, off-white ointment, free from foreign matter.

### - Ingredients

Active ingredients:

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Each gram 0.64 mg of betamethasone dipropionate, equivalent to 0.5 mg (0.05% w/w) of betamethasone, and 30 mg (3% w/w) of salicylic acid.

Inactive ingredients:

White petroleum and mineral oil.

- *MAL number:*

MAL19871163AZ

## **Manufacturer**

S-P Canada, 3535 TransCanada, Pointe-Claire, Quebec, Canada H9R 1B4 under authority of Merck & Co., Inc., Whitehouse Station, NJ, U.S.A.

## **Product Registration Holder**

Merck Sharp & Dohme (Malaysia) Sdn. Bhd.  
T2-9, Jaya 33, No. 3 (Lot 33)  
Jalan Semangat, Seksyen 13  
46100 Petaling Jaya, Selangor, Malaysia.

## **Date of Revision**

25/03/2016

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