

BETAPROSALIC OINTMENT

Betamethasone Dipropionate, Salicylic Acid (0.05%w/w, 3.00%w/w)

What is in this leaflet

1. What is Betaprosalic Ointment used for
2. How Betaprosalic Ointment works
3. Before you use Betaprosalic Ointment
4. How to use Betaprosalic Ointment
5. While you are using it
6. Side effects
7. Storage and Disposal of Betaprosalic Ointment
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Betaprosalic Ointment is used for

Betaprosalic Ointment is indicated for relief from inflammatory manifestations of hyperkeratotic and dry corticosteroid responsive dermatoses. This includes:

- Psoriasis (skin condition that causes red, flaky, crusty patches of skin covered with silvery scales).
- Chronic Atopic Dermatitis (condition that makes the skin red and itchy).
- Neurodermatitis (skin condition that begins with an itch).
- Lichen planus (non-infectious, itchy rash that can affect many areas of the body).
- Eczema (term for a group of medical conditions that cause the skin to become inflamed or irritated).
- Dyshidrosis (is a skin condition in which blisters develop on the soles of feet and/or the palms of hands)
- Seborrheic dermatitis of the scalp (common, inflammatory skin condition that causes flaky, white to yellowish scales to form on oily areas such as the scalp. It can occur with or without reddened skin).

- Ichthyosis vulgaris (skin condition that causes dry, dead skin cells to accumulate in patches on the surface of the skin).
- Other ichthyotic (a congenital, often hereditary skin disease marked by dry, thickened, scaly skin) conditions.

How Betaprosalic Ointment works

Betaprosalic Ointment contains two active ingredients which are betamethasone dipropionate and salicylic acid

Betamethasone dipropionate belongs to a group of medicines known as topical corticosteroids. It is classified as '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 the skin problem. This allows the betamethasone dipropionate to reach the diseased skin underneath to help heal it.

In adults and children, Betaprosalic Ointment is used to treat skin conditions where the outer surface of the skin is covered by a layer of scales. The ointment will remove the layer of scales and reduce the redness and itchiness caused by the skin problem

Before you use Betaprosalic Ointment

- When you must not use it

- If you have an allergy to Betamethasone dipropionate, salicylic acid or any of the other ingredients in this medicine.
- If you are suffering with:
 - Most viral skin lesions, particularly herpes simplex (a viral infection), vaccinia (cowpox), varicella (chickenpox).
 - 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 or anal itching.

- If you have nappy rash, fungal or bacterial skin infections without suitable concomitant anti-infective therapy or other skin conditions.

- Before you start to use it

Always be reminded these when

Using **Betaprosalic Ointment**

- Do not use occlusion; it may lead to enhanced absorption of the steroid.
- Avoid long term usage.
- When the medicine is applied topically particularly to large areas, broken skin or under occlusive dressings, corticosteroids may be absorbed in sufficient amounts to cause systemic effects.
- When having an infection, an appropriate antifungal or antibacterial agent should be used.
- Avoid contact with the eyes and mucous membranes.
- If excessive dryness, irritation or sensitisation develops with the use of Betaprosalic Ointment treatment should be discontinued.

Betaprosalic Ointment should not be applied to large areas of the body, for prolonged periods of time or under occlusion as it may cause toxicity.

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.

BETAPROSALIC OINTMENT

Betamethasone Dipropionate, Salicylic Acid (0.05%w/w, 3.00%w/w)

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.

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

Pregnancy and lactation

- Do not take Betaprosalic Ointment if you are pregnant or plan to become pregnant or think you might be pregnant. If you get pregnant while taking Betaprosalic Ointment, stop taking it immediately and contact your doctor.
- Do not take Betaprosalic Ointment if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Taking other medicines

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

How to use Betaprosalic Ointment

- How much to use

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- When to use it

For adults and children:

Apply a thin layer of betaprosalic ointment into the affected area and rubbed gently. It can be applied twice a day.

You should follow these instructions when using betaprosalic ointment:

- 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.

- How long to use it

Continue taking your medicine for as long as your doctor or pharmacist tells you.

- If you forget to use it

If you forget to use your ointment at the right time, use it as soon as you remember, then carry on as before.

- If you use too much (overdose)

If you think you or anyone else may have taken too much of this medicine, contact your doctor immediately. Excessive prolong use or on large areas of your body, it can affect the levels of certain hormones in the body and lead to Cushing's disease (a

metabolic disorder involving obesity and high blood pressure.)

Topically ointment with salicylic acid with prolonged use may cause toxicity with symptoms (ringing in the ears, nausea, and vomiting.)

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 and immediate treatment should be taken accordingly.

While you are using it

- Things you must do

- Take your ointment exactly as your doctor has told you.

- Things you must not do

- Do not stop taking the ointment unless advised by your doctor.
- 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.
- Do not put the ointment under your child's nappy.

- Things to be careful of

Side effects

Like all medicines, Betaprosalic Ointment can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any of the side effects after taking this medicine:

- Thinning of the skin.
- Stinging, blistering, peeling, swelling, itching, burning, skin rash, dryness of the skin and red marks. This can happen more easily in infants and children.
- Inflammation of the hair follicles.
- Excessive hair growth.
- Reduced skin pigmentation.
- Allergic skin reactions.

BETAPROSALIC OINTMENT

Betamethasone Dipropionate, Salicylic Acid (0.05% w/w, 3.00% w/w)

- Skin Inflammation (dermatitis) – a condition brought on by the skin reacting to outside agent such as detergents, causing the skin to become red and itchy.

Manufacturer and Product Registration Holder
NORIPHARMA SDN. BHD.(792633A)

Lot 5030, Jalan Teratai. 51/2 Mile Off Jalan Meru, 41050 Klang, Selangor, Malaysia.

Date of revision
- 21/05/2019

Serial Number
NPRA (R2)19/109

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Betaprosalic Ointment.

- Storage

- Store below 30°C
- Keep container well closed and 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

Betaprosalic Ointment: A white to pale yellow, smooth ointment.

- Ingredients

Active ingredient

- Betamethasone Dipropionate
- Salicylic Acid

Inactive ingredients

- Liquid Paraffin
- White Soft Paraffin

- MAL number:

MALxxxxxxx