

PHARMANIAGA DERMAL SA OINTMENT

Betamethasone dipropionate/Salicylic acid (0.05% w/w / 3% w/w)

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What Pharmaniaga Dermal SA Ointment is used for

It is used to treat skin inflammation such as psoriasis, chronic atopic dermatitis, eczema, neurodermatitis, lichen planus, seborrhoeic dermatitis and other conditions in which the skin is coarse, dry, and scaly.

How Pharmaniaga Dermal SA Ointment works

Betamethasone dipropionate is one of a group of medicines called topical corticosteroids. It is classified as a "potent corticosteroid". This medicine is 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.

Before you use Pharmaniaga Dermal SA Ointment

-When you must not use it

- If you are allergic to corticosteroids, salicylic acid or

propylene glycol or other ingredients in this product.

- If you are suffering with:
 - Untreated bacterial, fungal or viral skin lesions
 - Redness on the face
 - Red spotty rash around your mouth or chin.

Pregnancy and lactation

Do not use Pharmaniaga Dermal SA Ointment if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not use Pharmaniaga Dermal SA Ointment if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine as it may cause unwanted effects in the infant such as growth suppression. Salicylic acid may also be systemically absorbed.

-Before you start use it

Always be reminded these when using Pharmaniaga Dermal SA Ointment:

- 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. If a favourable response does not occur promptly, the corticosteroid should be discontinued until the infection has been controlled adequately.
- Salicylic acid should not be applied to large areas of the body, for prolonged periods of time or under occlusion in young children as it may cause toxicity.

-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 Pharmaniaga Dermal SA Ointment

Your doctor will tell you how frequent to apply Pharmaniaga Dermal SA Ointment. This should also be printed on the product label. The medicine should not be used under bandages or plasters.

-How much to use

A thin layer of Pharmaniaga Dermal SA Ointment should be gently applied into the affected area of skin twice a day, up to a maximum of 60g weekly.

Treatment should be discontinued when the skin disorder is controlled.

-When to use it

Use as directed by your doctor or pharmacist.

-How long to use it

Continue taking Pharmaniaga Dermal SA Ointment for as long as your doctor recommends. This medicine is usually used for short period of time.

-If you forget to use it

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

-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.

Topically ointment can be absorbed in sufficient amounts to produce systemic effects. Symptoms include confusion,

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dizziness, headache, rapid breathing, ringing or buzzing in ears.

While you are using it

-Things you must do

Use your medicine exactly as your doctor has told you.

Talk to your pharmacist or doctor if your symptoms do not improve. Your pharmacist or doctor will assess your condition and decide if you should continue to use the medicine.

Tell all the doctors, dentists and pharmacists treating you that you are on Pharmaniaga Dermal SA Ointment.

-Things you must not do

Do not stop applying the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Pharmaniaga Dermal SA Ointment to anyone else; even they have the same symptoms or condition as you.

-Things to be careful of

Pharmaniaga Dermal SA Ointment should be avoided in children below 1 year of age or if necessary, used with great care for only short period of time.

Side effects

Like all medicines, Pharmaniaga Dermal SA Ointment can cause side effects, although not everybody gets them.

The following side effects are reported infrequently when topical corticosteroids are used as recommended. It is included:-

- Burning, itching, irritation, dryness on skin.

- Hair follicle inflammation, excessive hair growth
- Acne eruption
- Allergic contact skin inflammation
- Maceration of the skin (surrounding of the wound skin has too much moisture and causing it to turn white and soften).

“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 npra.moh.gov.my (Public Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of Pharmaniaga Dermal SA Ointment

-Storage

Keep all medicines out of the sight and reach of children.

Keep the medicines in a cool dry place where the temperature stays below 25°C. Protect from light. Keep container tightly closed.

Do not store in the bathroom or near a sink, or on a window sill.

Do not leave it in the car on hot days. Heat and dampness can destroy some medicines.

Do not take this medicine after the expiry date stamped on the pack. The expiry date refers to the last day of that month.

-Disposal

Medicines should not be disposed off 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

A smooth clear ointment.

-Ingredients

-Active ingredients:

Betamethasone dipropionate 0.05% w/w and salicylic acid 3.0% w/w

-Inactive ingredients:

White soft paraffin and Liquid paraffin.

-MAL number:

MAL19987988AZ

Manufacturer

Pharmaniaga Manufacturing Berhad (60016-D),
11A, Jalan P/1,
Kawasan Perusahaan Bangi,
43650 Bandar Baru Bangi,
Selangor Darul Ehsan, Malaysia.

Product Registration Holder

Pharmaniaga Manufacturing Berhad (60016-D),
11A, Jalan P/1,
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