

PHARMANIAGA DERMASOLE CREAM

Betamethasone valerate (0.1% w/w)

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What Pharmaniaga Dermasole Cream is used for

Pharmaniaga Dermasole Cream is a potent topical corticosteroid that produces a satisfactory response in a short time in those inflammatory skin conditions that are normally responsive to topical corticosteroid therapy, and is also effective in the less responsive conditions such as psoriasis.

It is indicated for the treatment of:

- Eczema, including atopic, infantile, discoid and stasis eczema
- Chronic itchy skin such as prurigo, neurodermatoses including lichen simplex and lichen planus.
- Psoriasis (skin disorder with raised, rough, reddened areas covered with dry, fine silvery scales).
- Seborrhoeic dermatitis (skin inflammation that mainly affects the scalp).
- Intertrigo (inflammation of the body folds).
- Contact sensitivity reactions.
- Discoid lupus erythematosus (recurring scaly rash).
- Generalised erythroderma (intense and usually widespread reddening and scaling of the skin due to inflammatory skin disease).

How Pharmaniaga Dermasole Cream works

Pharmaniaga Dermasole Cream contains the active ingredient called betamethasone. Betamethasone belongs to a group of medicine called steroid. It helps to reduce swelling and inflammation.

Before you use Pharmaniaga Dermasole Cream

- *When you must not to use it*

Do not use Pharmaniaga Dermasole Cream:

- If you are allergic to Betamethasone or corticosteroids or any other ingredients contained in this medicine as listed at the end of this leaflet.
- If you have Rosacea (redness on your face).
- If you have peri-oral dermatitis (facial rash that causes bumps to develop around the mouth).
- If you have skin lesions caused by infection with viruses (e.g. herpes simplex, chickenpox), fungi (e.g. candidiasis, tinea) or bacteria (e.g. impetigo).

Pregnancy and lactation

Do not use Pharmaniaga Dermasole Cream extensively in pregnancy, i.e. in large amounts or for prolonged periods. If you are pregnant, trying to get pregnant or think you may be pregnant, discuss it with your doctor first.

Do not use Pharmaniaga Dermasole Cream if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

If you are not sure whether you should start using this medicine, talk to your doctor or pharmacist.

- *Before you start use it*

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

The face, more than other areas of the body, may exhibit thinning effects after prolonged treatment with potent topical corticosteroids. This must be borne in mind when treating such conditions as psoriasis, discoid lupus erythematosus and severe eczema with betamethasone. Application to the eyelids may cause increased eye pressure.

Appropriate therapy should be used when infections are present. Any spread of infection requires withdrawal of topical corticosteroid therapy and systemic use of anti- microbial agents. Bacterial infection is encouraged by the warm, moist conditions induced by occlusive dressings, and the skin should be cleansed before fresh dressing is applied.

- *Taking other medicines*

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

How to use Pharmaniaga Dermasole Cream

Always use the medicine exactly as your doctor or pharmacist has told you. Read the direction labels carefully. If you have any concerns about how to use this medicine, talk to your doctor or pharmacist.

- *How much to use*

Your doctor will advise you how much to use each day, and for how long you will need to use.

A small quantity is applied lightly to the affected area two or three times daily until improvement. It may then be possible to maintain progressive improvement using one application a day or even less often.

Occlusion of the area under treatment with plastic film may be used to enhance corticosteroid

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activity in the more resistant lesions. Overnight occlusion only is usually adequate to bring about a satisfactory response in such cases thereafter, improvement can usually be maintained by regular application without occlusion.

-When to use it

Use as directed by your doctor or pharmacist.

-How long to use it

Continue taking Pharmaniaga Dermasole Cream for as long as your doctor recommends.

-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 take too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using Pharmaniaga Dermasole Cream

-Things you must do

Use the medication exactly as your doctor prescribed.

- This medicine is for external use only.
- Wash your hands before and after using this medication.
- Tell all the doctors, dentists and pharmacists treating you that you are using Pharmaniaga Dermasole Cream.

- Tell your doctor immediately if you become pregnant while taking this medication.

-Things you must not do

- Do not give Pharmaniaga Dermasole Cream to anyone else, even if their symptoms seem similar to yours.
- Do not use your medicine to treat any other complaints unless your doctor or pharmacist tells you to.
- Prevent this medicine from getting into your eyes.

-Things to be careful of

If irritation, sensitization or allergic reaction occurs, stop using it and ask your doctor.

Side Effects

Like all medicines, Pharmaniaga Dermasole Cream can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

Prolonged and intensive treatment with highly active corticosteroid preparations may cause local changes in the skin such as stretch mark, thinning and dilatation of the superficial blood vessels, particularly when occlusive dressings are used or when skin folds are involved.

As with other topical corticosteroids, prolonged use of large amounts or treatment of extensive areas, can result in sufficient systemic absorption to produce the features of hypercorticism (high cortisol hormones).

This effect is more likely to occur in infants and children, and when occlusive dressing is used. In infants, napkin may act as an occlusive dressing.

Other side effects not listed above may occur in some people. Ask your doctor or pharmacist to answer any questions you may have.

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 np.ra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

Storage and disposal of Pharmaniaga Dermasole Cream

- Storage

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

Do not use this medicine after the expiry date stamped on the pack.

Store below 25°C. Keep container tightly closed. 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

A white, soft cream, free from foreign matter.

- Ingredients:

-Active ingredient(s):- Betamethasone (as 17-valerate) (0.1% w/w).

-Inactive ingredient(s):-

Liquid paraffin, Sodium dihydrogen phosphate dihydrate, Chlorocresol, Cetomacrogol, White Soft Paraffin, Cetostearyl Alcohol, Purified Water.

-MAL Number(s):-

MAL19870620AZ

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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
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