## PHARMANIAGA DERMAPRO OINTMENT

Clobesatol Propionate (0.05% w/w)

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# What Pharmaniaga Dermapro is used for

PHARMANIAGA DERMAPRO is used for short-term treatment of inflammation and/or itchy skin disorders that is responding to steroids.

## How Pharmaniaga Dermapro works

PHARMANIAGA DERMAPRO contains a medicine called Clobetasol Propionate. Clobetasol Propionate belongs to a group of medicines called high potency steroids which has anti-inflammatory action. It helps to reduce swelling and irritation.

## Before you use Pharmaniaga Dermapro

## - When you must not use it

Do not use PHARMANIAGA DERMAPRO if you are allergic (hypersensitive) to Clobesatol Propionate or other ingredients in this product

#### Pregnancy and lactation

Do not use PHARMANIAGA DERMAPRO if you are pregnant, trying to get pregnant or think you may be pregnant. Clobetasol should not be used extensively on pregnant women, in large amounts, or for prolonged periods of time.

Do not use PHARMANIAGA DERMAPRO if you are breast-feeding. Systemic corticosteroids are found in breast milk and may cause unwanted effects in the infant such as growth suppression. Ask your doctor or pharmacist for advice before taking any medicine.

#### - Before you start to use it

Check with your doctor or pharmacist before using your medicine:

- If you have any areas of infected skin
- If you have psoriasis
- If you have redness or acne on the face
- If you have small bumps around the mouth

#### - 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 Dermapro

#### - How much to use

Follow all directions given to you by your doctor and 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.

#### Usual adult dosage:

Apply a thin film to the affected area two or three times a day up to a maximum of 50 g per week.

#### Usual children dosage:

Use is not recommended in children up to 12 years of age.

Treatment should be limited to two consecutive weeks and total dose should not exceed 50 g per week.

### - When to use it

Use as directed by your doctor or pharmacist.

## - How long to use it

Continue taking PHARMANIAGA DERMAPRO for as long as your doctor recommends. The duration of therapy should be limited to brief periods.

#### - If you forget to use it

If you forgot to use the cream/ointment, apply PHARMANIAGA DERMAPRO again when you remember.

#### - If you use 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 it

#### - Things you must do

Tell all the doctors, dentists and pharmacists treating you that you are taking PHARMANIAGA DERMAPRO.

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

#### - Things you must not do

Clobetasol products are not to be used in the eye, to be avoided on the face, groin or armpit.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give PHARMANIAGA DERMAPRO to anyone else, even if they have the same symptoms or condition as you.

## - Things to be careful of

Do not stop taking the medicine without talking to your doctor or pharmacist first, otherwise the original pain and discomfort may come back. If you have any further questions on the use of this product, ask your doctor or pharmacist.

Stop using PHARMANIAGA DERMAPRO and tell your doctor as soon as possible if:

- You find that your skin condition gets worse or becomes swollen during treatment. You may be allergic to the PHARMANIAGA DERMAPRO, have an infection or need other treatment.
- You have psoriasis you may get raised bumps with pus under the skin. When applied topically, particularly to large areas, or when the skin is broken, or under occlusive dressings, corticosteroids may be absorbed in sufficient amounts to cause systemic effects, resulting in reversible adrenal gland suppression.

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#### Side effects

Like all medicines, PHARMANIAGA DERMAPRO can cause side effects, although not everybody gets them.

The side effects when using PHARMANIAGA DERMAPRO:

- Loss of skin collagen and skin thinning, local loss of skin colour of deeply pigmented skins, burning and stinging sensation, itching
- Veins under the surface of your skin may become more noticeable

Children and adolescents may demonstrate greater susceptibility to adrenal gland suppression, Cushing's syndrome (moon face, thinning of skin with bruising tendency and facial hair growth), high pressure in the skull, and growth retardation. This is due to larger skin surface area to body-weight ratio which results in greater amount of systemic absorption.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835549, or visiting the website <a href="mailto:npra.moh.gov.my">npra.moh.gov.my</a> (Public →Reporting Medicinal Problems / Side Effects (ConSERF) or Vaccine (AEFI)).

# Storage and Disposal of PHARMANIAGA DERMAPRO

#### - Storage

Keep out of the reach and sight of children. Store below 25°C. Protect from light. Do not use PHARMANIAGA DERMAPRO after the expiry date which stated on the label

#### - 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 smooth white ointment

- Ingredients
  - Active ingredient Clobetasol Propionate 0.05% w/w

Inactive ingredients
 Cetostearyl Alcohol, Propylene
 Glycol, Cetomacrogol and White soft paraffin.

#### - MAL numbers:

## PHARMANIAGA DERMAPRO OINTMENT 0.05%w/w MAL19984845AZ

#### 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, Kawasan Perusahaan Bangi, 43650 Bandar Baru Bangi, Selangor Darul Ehsan, Malaysia.

#### **Date of revision**

29/06/2018

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