# **CLODERM OINTMENT**

Clobetasol Propionate (0.05% w/w)

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This leaflet answers some common questions about Cloderm Ointment. It does not contain all the available information. It does not take the place of talking to your pharmacist or doctor.

All medicines have risks and benefits. Your pharmacist or doctor has weighed the risks of you taking Cloderm Ointment against the benefits they expect it will have for you.

Keep this leaflet with the medicine.

You may need to read it again.

# What Cloderm Ointment is used for

Cloderm Ointment is used for short-term treatment of inflammatory and itching manifestations of moderate to severe corticosteroid-responsive skin disease.

#### **How Cloderm Ointment works**

Cloderm Ointment contains a medicine called clobetasol propionate. It belongs to a group of medicines called steroids. It has anti-inflammatory, anti-itching and blood vessel narrowing actions.

Ask your pharmacist or doctor if you have any questions about this medicine.

#### Before you use Cloderm Ointment

#### -When you must not use it

Do not take Cloderm Ointment if:

- You are hypersensitive to any of this medicine related ingredients.
- You have viral skin infections (e.g. Herpes simplex, chicken pox), acne, skin redness
- You have peri-oral skin inflammation and itching.
- You have skin infection caused by fungi or bacteria.
- You have genital itching.

Not recommended for infants under 1 year of age.

If you are not sure, talk to your doctor or pharmacist before using Cloderm Ointment.

#### -Before you start to use it

Pregnancy and breast feeding:

- Safe use during pregnancy and lactation has not been established.
- Ask your doctor or pharmacist for advice before taking this medicine if you are pregnant or breast-feeding.

### -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 Cloderm Ointment**

#### -How much to use

Apply Cloderm Ointment sparingly to the affected areas and rub in once or twice daily as directed by your doctor and pharmacist.

## -When to use it

Apply on the affected area once dry and clean.

#### -How long to use it

Consult with your doctor or pharmacist for the treatment period.

#### -If you forget to use it

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

## -If you use too much (overdose)

In sufficient amount, steroid can pass through your skin to produce systemic effect such as high blood glucose level, presence of glucose in the urine and Cushing's syndrome (Please refer to 'Side effects Section').

If you suspect that you are overdosed, please consult your pharmacist or doctor. Bring any remaining medicine with you.

# While you are using Cloderm Ointment

### -Things you must do

If you are about to start taking on any other new medicine, tell your pharmacist or doctor that you are taking Cloderm Ointment.

If symptoms persist please consult your doctor or pharmacist.

This preparation is for the treatment of your current conditions only.

## -Things you must not do

Do not take more than the recommended dose unless your doctor tells you to.

Not suitable for eye use.

Do not allow use by any other person and dispose of unused material when your treatment is complete.

## -Things to be careful of

Discontinue use if irritation or sensitivity reaction develops. Suitable precautions should be taken during prolonged treatment, when treating extensive body surface areas and when treating children (because of a larger skin surface area to body weight ratio as systemic absorption will cause growth retardation).

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#### Side effects

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

Reported local adverse reactions are burning sensation, itching, irritation, dryness, folliculitis (an infection in the hair follicles), hypertrichosis (abnormal amount of hair growth over the body), acneiform eruptions (acne like lesions), hypopigmentation (the loss of skin color), maceration of the skin (the softening and breaking down of skin), skin atrophy (the upper layers of skin get thin), striae (stretch mark) and miliria (sweat rash).

Large doses of corticosteroids may produce symptoms typical of hyperactivity of the adrenal gland, with moon face, sometimes with hirsutism (excessive hair growth in certain areas of a woman's face and body), buffalo hump (deposition of fat in the area behind the base of the neck), flushing (red condition of human skin), sometimes leading to a fully developed Cushing's syndrome.

If you get any side effects, even those not mentioned in this leaflet, 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: 03-78835550, or visiting the website <a href="mailto:npra.moh.gov.my">npra.moh.gov.my</a> (Public → Reporting Medicinal Problem / Side Effects / AEFI / Vaccine Safety).

# Storage and Disposal of Cloderm Ointment

-Storage
Store below 30°C.
Keep container well closed.
Protect from strong light.
Keep out of reach of children.

#### -Disposal

Dispose the medicine after the expiry date. 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

Cloderm Ointment is a white ointment.

Cloderm Ointment available in aluminium tubes of 5g, 15g and 100g.

### -Ingredients

-Active ingredient(s): Each tube contains Clobetasol Propionate 0.0568% w/w (equivalent to Clobetasol 0.05% w/w).

-Inactive ingredients: White Soft Paraffin, Liquid Paraffin.

<u>-MAL number:</u> MAL19930241AZ

#### Manufacturer

HOE Pharmaceuticals Sdn. Bhd. Lot 10, Jalan Sultan Mohamed 6, Bandar Sultan Suleiman, 42000 Port Klang, Selangor, Malaysia.

#### **Product Registration Holder:**

HOE Pharmaceuticals Sdn. Bhd. Lot 10, Jalan Sultan Mohamed 6, Bandar Sultan Suleiman, 42000 Port Klang, Selangor, Malaysia.

#### **Date of revision**

-13/06/2017

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