

# DAIVOBET® OINTMENT

Calcipotriol/betamethasone Dipropionate (50mcg/0.5mg per gram)

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## What Daivobet Ointment is used for

Daivobet Ointment is used on the skin to treat plaque psoriasis (psoriasis vulgaris) which is amenable to topical therapy. Psoriasis is caused by your skin cells being produced too quickly. This causes redness, scaling and thickness of your skin.

## How Daivobet Ointment works

Calcipotriol is a vitamin D analogue that helps to bring the rate of skin cell growth back to normal. Betamethasone is a steroid that acts to reduce inflammation.

## Before you use Daivobet Ointment

### -When you must not use it

- If you are allergic (hypersensitive) to calcipotriol, betamethasone,

or any of the other inactive ingredients of Daivobet.

- If you have problems with calcium levels in your body (ask your doctor)
- If you have certain types of psoriasis that is inflamed with intense redness, peeling and/or blister.
- If you want to use for children below 18 years old
- As Daivobet contains a strong steroid do NOT use on skin affected by
  - Skin infections caused by viruses, fungus, bacteria or parasites
  - Perioral dermatitis (red rash around the mouth)
  - Thin skin, easily damaged veins, stretch marks
  - Ichthyosis (inherited dry, thickened, scaly skin)
  - Acne
  - Rosacea (redness on face)
  - Ulcers or broken skin

### *Pregnancy and lactation*

Do not use Daivobet if you are pregnant (or might be pregnant) or if you are breast-feeding, unless you have agreed with your doctor first. If your doctor has agreed that you can breast-feed, take care and do not apply Daivobet to the breast area.

Ask your doctor or pharmacist for advice before taking any medicine

### -Before you start to use it

Remove the cap and check that the seal in the tube is not broken before you first use the ointment  
Wash your hands before application  
Please inform your doctor if you have diabetes.

### -Taking other medicines

Tell your doctor or pharmacist 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 Daivobet Ointment

Always use Daivobet exactly as advised by your doctor. Check with your doctor or pharmacist if unsure. Daivobet should be applied to the skin. Do not use on skin which does not have psoriasis.

### -How much to use

The maximum daily dose should not exceed 15 g.  
The body surface area treated with calcipotriol containing medicinal products should not exceed 30%.

### -When to use it

Daivobet® should be applied to affected areas once a day. Use as directed by your doctor or pharmacist.

### -How long to use it

The usual recommended treatment period is 4 weeks. Your doctor may decide on a different treatment plan.

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## After applying Daivobet ointment

- Do not bandage, tightly cover or wrap the treated skin area
- Wash your hands well after using Daivobet (unless you are using the ointment to treat your hands). This will avoid accidentally spreading the ointment to other parts of your body especially face, mouth and eyes
- Do not worry if some ointment accidentally gets on normal skin near your psoriasis, but wipe it off if it spreads too far
- In order to achieve optimal effect, it is recommended not to take a shower or bath immediately after application of Daivobet ointment
- After applying the ointment avoid contact with textiles which are easily stained by grease.
- Avoid excessive sunbathing, excessive use of solarium and other forms of light treatment

## -If you forget to use it

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

Do not take a double dose to make up for the missed dose.

## -If you use too much (overdose)

Use above the recommended dose or more than 15grams a day may cause problems of high calcium levels in your blood. This should rapidly subside when treatment is discontinued. Your doctor may need to carry out blood tests to check that using too much ointment has not caused a problem with calcium in your blood. Excessive prolonged use can also cause your adrenal glands to stop functioning properly.

## **While you are using it**

### -Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Daivobet Ointment.

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

### -Things you must not do

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

Do not take any new medicines without consulting your doctor.

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

### -Things to be careful of

Effects on the ability to drive and use machines:

Daivobet® has no or negligible influence on the ability to drive and use machines.

## Adverse reactions to excipients:

Daivobet® ointment contains butylhydroxytoluene (E321) as an excipient. This may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

Application on mucous membranes or in skin folds should be avoided

Daivobet® and concurrent treatment with other steroids on the same treatment area must be avoided. Skin of the face and genitals are very sensitive to corticosteroids. The medicinal product should not be used in these areas.

When lesions become secondarily infected, they should be treated with antimicrobiological therapy. However, if infection worsens, treatment with corticosteroids should be stopped.

There is limited experience for the use of this product on the scalp.

## **Side effects**

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

Tell your doctor/pharmacist/nurse immediately or as soon as possible and stop using Daivobet if any of the following happens.

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## Serious Side Effects

- Worsening of psoriasis
- Pustular psoriasis may occur (a red area with yellowish pustules usually on the hands or feet).
- Adrenal glands may stop functioning properly. Signs are tiredness, depression and anxiety
- Cataracts or an increase in pressure inside the eye
- Infections
- Impact on the metabolic control of diabetes
- Allergic reactions (deep swelling of the face or other parts of the body such as the hands or feet. Swelling of the mouth/throat and trouble breathing may occur.) When such occur, seek medical attention immediately.
- Signs of elevated calcium in blood such as excessive urination, constipation, muscle weakness, confusion and coma. This can be serious, seek medical attention immediately.

## Less Serious Side Effects

- Skin exfoliation
- Itching
- Inflammation or swelling of the hair roots
- Thinning of the skin
- Rash with or without inflammation of the skin
- Redness of the skin due to widening of the small blood vessels
- Skin irritation or pain (burning sensation)
- Discoloration (red/purple) or lightening in skin color in the area you have applied the ointment

- Stretch marks
- Sensitivity of the skin to light resulting in a rash
- Acne (pimples)
- Dry skin
- Eczema

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](http://npra.moh.gov.my) (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

## **Storage and Disposal of Daivobet Ointment**

### -Storage

- Keep out of the reach and sight of children
- Do not use Daivobet after the expiry date.
- Do not store above 30°C.
- Discard the tube after 12 months after first opening. Write the date you first opened the tube on the carton as a reminder.

### -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

Off-white to yellow coloured ointment.

### -Ingredients

- Active ingredient(s)
  - Calcipotriol 50 micrograms per gram (as hydrate)
  - betamethasone 0.5 mg per gram (as dipropionate).
- Inactive ingredients
  - Liquid paraffin
  - polyoxypropylene stearyl ether (containing butylhydroxytoluene [E321])
  - all-rac- $\alpha$ -tocopherol
  - white soft paraffin

### -MAL number:

MAL20040816AZ

## **Manufacturer**

Leo Labs LTD  
Cashel Road, Dublin 12,  
Ireland

## **Product Registration Holder**

DKSH Malaysia Sdn Bhd  
B-11-01, The Ascent, Paradigm  
No. 1, Jalan SS7/26A, Kelana Jaya  
47301 Petaling Jaya  
Selangor  
Malaysia.

## **Date of revision**

02/02/2018

## **Serial Number**

NPRA(R4/1)121217/00357