

CALCIBET Ointment

Consumer Medication Information Leaflet (RiMUP)

Calcipotriol 50mcg/g and Betamethasone 0.5mg/g

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What is CALCIBET Ointment used for

CALCIBET Ointment used for topical treatment of psoriasis vulgaris.

How CALCIBET Ointment works

CALCIBET Ointment contains calcipotriol and betamethasone.

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 CALCIBET Ointment

- When you must not use it

- If you are allergic (hypersensitive) to calcipotriol, betamethasone, or any of the other inactive ingredients of CALCIBET Ointment.
- 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 CALCIBET Ointment 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 CALCIBET Ointment 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 CALCIBET Ointment 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 CALCIBET Ointment.

Wash your hands before application.

Please inform your doctor if you have diabetes.

- Taking other medications

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

As this drug contains a potent group III steroid, concurrent treatment with other steroids on the scalp must be avoided.

Concurrent administration with salicylic acid must be avoided. Salicylic acid may decrease the effect of calcipotriol.

Concurrent administration with other psoriasis product and other forms of light treatment was not experienced.

How to use CALCIBET Ointment

- 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

CALCIBET Ointment 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.

After applying CALCIBET Ointment

- Do not bandage, tightly cover or wrap the treated skin area.
- Wash your hands well after using CALCIBET Ointment (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 CALCIBET 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.

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

- If you use too much (overdose)

Contact your doctor if you have used more than 15 grams in one day. Excessive use of CALCIBET Ointment may cause a problem with calcium in your blood, which usually normalises when discontinuing treatment. 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 working properly (these are found near the kidneys and produce hormones).

While you are using it

- Things you must do

Take your medicine exactly as your doctor as told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking CALCIBET 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 CALCIBET 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:

CALCIBET Ointment has no or negligible influence on the ability to drive and use machines.

Adverse reactions to excipients: CALCIBET 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.

CALCIBET Ointment 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 antimicrobial 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, CALCIBET Ointment can cause side effects, although not everybody gets them.

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

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 visiting the website npra.gov.my [Consumers Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of product name

- Storage

Store below 30°C.

Keep the medicine out of reach of children.

- 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 pale yellow or yellow ointment.

- Ingredients

- Active ingredients:
Calcipotriol Monohydrate

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Betamethasone Dipropionate

- Inactive ingredients:

White Petrolatum

Liquid Paraffin

Polyoxypropylene

stearyl ether

Tocopherol Acetate

- MAL number: MAL22046016AZ

Manufacturer

GENUONE Sciences Inc.

245, Sandan-gil, Jeonui-myeon,

Sejong-si, Republic of Korea

Product Registration Holder

Healol Pharmaceuticals Sdn. Bhd.

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KLSC Wangsa Maju, 53300 Kuala

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