

DAIVOBET(R) 50/500

Ointment

Dye-vo-bet

Calcipotriol (*Kal-sippo-try-all*)/Betamethasone (*Beet-ah-meth-ah sown*)

CONSUMER MEDICINE INFORMATION

Please read this leaflet carefully before you start your treatment.

What is in this leaflet?

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

All medicines have risks and benefits. Your doctor has weighed the risks of you using Daivobet ointment against the benefits it is expected to have for you.

If you have any concerns about using Daivobet ointment, talk to your doctor or pharmacist.

Daivobet is the brand name. Calcipotriol and betamethasone are the generic names of the combination product, which is Daivobet ointment.

Keep this leaflet.

You may want to read it again.

What Daivobet ointment is used for

Daivobet ointment is an anti-psoriasis medicine. Daivobet ointment contains two active ingredients:

- * calcipotriol (related to Vitamin D);
- * betamethasone dipropionate (a corticosteroid).

Daivobet ointment is used only on skin affected by plaque-type psoriasis. Psoriasis is a skin disorder in which skin cells are overactive. The calcipotriol in Daivobet ointment treats the overactive skin cells. The betamethasone dipropionate relieves redness, swelling, itching and irritation of the skin.

Daivobet ointment is used in the type of psoriasis, where "plaques" form in the skin. Plaques are raised, rough, reddened areas covered with fine, dry silvery scales. Plaques are usually about one to two centimetres across.

Daivobet ointment is available only with a doctor's prescription.

This medicine is not expected to affect your ability to drive a car or operate machinery.

This medicine is not addictive.

Before you use Daivobet ointment

When you must not use Daivobet ointment

Do not use Daivobet ointment if you have an allergy to:

- * calcipotriol
- * betamethasone dipropionate
- * any of the other ingredients listed

at the end of this leaflet (see Product description)

- * any other similar medicine, such as topical corticosteroids.

Some of the symptoms of an allergic reaction include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or "hives" on the skin.

Do not use Daivobet ointment for severe widespread psoriasis, or the types of psoriasis known as generalised pustular or erythrodermic exfoliative psoriasis.

Your doctor will identify these conditions for you.

Do not use Daivobet ointment if you

- * have high blood calcium levels;
- * are taking calcium supplements, drugs to treat calcium deficiency, vitamin D supplements or vitamin D-like medicines, for example calcitriol;
- * have kidney or liver problems;
- * have any viral, fungal or bacterial skin infections.

Inform your doctor if you are suffering from any illness before using Daivobet ointment.

Do not use Daivobet ointment

- * **after the expiry date printed on the pack OR**
- * **if it is 3 months after the tube**

was first opened OR

- * if the packaging is torn, doesn't look quite right or shows signs of tampering.

If any of these apply, return Daivobet ointment to your pharmacist for disposal.

Do not breast-feed if you are using Daivobet ointment on your breasts.

If you are not sure whether you should start using Daivobet ointment, talk to your doctor.

Before you start to use it

Tell your doctor if you have a known allergy to Daivobet ointment, calcipotriol, betamethasone dipropionate or any of the ingredients listed at the end of this leaflet.

Tell your doctor if you

- * are pregnant
- * are breast-feeding
- * intend to breast-feed.

Do not use Daivobet ointment in children.

Safety and effectiveness of Daivobet ointment in those below 18 years of age has not been established.

If you have not told your doctor about any of the above, tell him/her before you start using this medicine.

Other medicines

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

Your doctor and pharmacist have more information on medicines you should be careful with or avoid whilst using Daivobet ointment.

How to use Daivobet ointment

Follow carefully all directions given to you by your doctor or pharmacist.

They may differ from the information contained in this leaflet.

If you do not understand the instructions in this leaflet, ask your doctor or pharmacist for help.

How much of Daivobet ointment to use

The area treated should not be more than 30% of the body surface.

Discuss this with your doctor.

Do not use more than 15 g in one day.

For example, no more than half (1/2) of a 30 g tube in one day.

Do not use more than 100 g in one week.

For example, no more than 3 tubes of 30 g in one week.

NOTE: If you use more than the recommended amount of Daivobet ointment, the levels of calcium in your blood may rise. This is known as "hypercalcaemia".

Hypercalcaemia:

- * is measured by a blood test;
- * may be harmful;
- * may mean that Daivobet ointment or any other product containing calcipotriol (eg; Daivonex) should not be used until the calcium level has become normal again.

Blood calcium levels will quickly normalise when your doctor discontinues treatment.

How to use Daivobet ointment

NOTE: unlike certain other skin preparations, which you use very sparingly, use Daivobet ointment as follows:

Apply Daivobet ointment only to the psoriasis plaques and gently rub in. If you accidentally put some of the ointment on normal skin, wash it off as soon as possible.

Do not use Daivobet ointment

- * on large areas of damaged skin;
- * in skin folds (eg. groin, underarm);
- * on the genitalia;
- * on the scalp;
- * inside the mouth, nose or in the eyes;
- * on the face. (An itchy red rash may develop).
- * under occlusive dressings (such as a bandage).

The treated area does not need to have a special covering. You may wear your usual clothes.

Wash your hands thoroughly after applying Daivobet ointment on any part of your body, unless your hands are being treated.

Take care not to get Daivobet ointment in your eyes. If this happens, rinse your eyes with clean water and tell your doctor.

Avoid getting Daivobet ointment on your face, scalp, mouth or eyes accidentally (see above).

If any skin irritation develops, wash off the Daivobet ointment.

When to use Daivobet ointment preparations

Apply Daivobet ointment once a day (either morning or night), unless otherwise directed by your doctor.

How long to use it

Continue to use Daivobet ointment for as long as your doctor tells you.

Your doctor may decide to stop Daivobet ointment treatment once your psoriasis has improved.

If you forget to use it

If you forget to use Daivobet ointment, use it as soon as you

remember. Then go on as before.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to use your medicine, ask your doctor or pharmacist for some hints.

If you use too much or use it other than directed (Overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26 in Australia or 0800 764 766/03 474 7000 in New Zealand) for advice, or go to the Emergency Department at the nearest hospital, if you think that you or anyone else may have used too much or swallowed some 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 Daivobet ointment

Things you must do

While you are using Daivobet ointment, protect the treated skin areas from sunlight and Ultra Violet (UV) rays, for example, by wearing protective clothing. This is particularly important if your job or lifestyle means you spend time out-of-doors.

If you are going to start any new medicine, tell your doctor and pharmacist that you are using Daivobet ointment.

If you become pregnant while using Daivobet ointment, tell your doctor immediately. Do not take other corticosteroids.

Keep all appointments with your doctor so that your progress can be checked.

Your doctor may do blood tests

whilst you are using Daivobet ointment (or any other product containing calcipotriol, for example Daivonex). These tests check the levels of calcium in your blood and how well your kidneys are working ("renal function").

Things you must not do

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not use more than the recommended daily or weekly dose (see How to use Daivobet ointment).

Do not use other topical corticosteroids (e.g. Advantan, Diprosone, Elocon) on areas treated with Daivobet ointment.

Side effects

As with all medicines, Daivobet ointment can cause some side effects.

Do not be alarmed by the following list of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist:

- * **if you have any unpleasant effects while you are using Daivobet ointment**
- or
- * **if you notice any of the following and they worry you:**
 - skin irritation (including itching, redness or burning, swelling, bruising, rashes or peeling)
 - a rash on your face or body
 - a change in the colour of your skin
 - your skin is more sensitive to light
 - headache
 - back pain
 - change in control of diabetes mellitus.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using Daivobet ointment

Keep Daivobet ointment in the box until required.

Storage

Keep your Daivobet ointment in a cool dry place where the temperature stays below 25 degrees C.

However, do not keep Daivobet ointment in the refrigerator, as the ointment will not spread easily.

Do not store Daivobet ointment or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep Daivobet ointment where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

Ask your pharmacist what to do with any Daivobet ointment that is left over if:

- * your doctor tells you to stop using Daivobet ointment, or
- * the tube has been opened for more than 3 months or
- * the expiry date has passed,

Product description

(R) = Registered Trade Mark

What it looks like

Daivobet ointment is an off-white to yellowish ointment.

Ingredients

Daivobet ointment contains the active ingredients

- * calcipotriol (50 microgram/g)
- * betamethasone dipropionate (0.5 milligram/g).

It also contains

- * paraffin - liquid
- * PPG-15-stearyl-ether
- * alpha-tocopherol
- * paraffin-soft white.

Daivobet ointment does not contain lactose, sucrose, gluten, tartrazine or any other azo products.

The Australian Registration Number is AUST R 98773

This is not all the information available on Daivobet ointment. If you have any more questions or are unsure about anything, ask your doctor or pharmacist.

Supplier

Daivobet ointment is supplied in Australia by:

CSL Limited ABN 99 051 588 348
45 Poplar Rd
Parkville 3052 VIC
AUSTRALIA

Daivobet ointment is manufactured by:

LEO Pharmaceutical Products
Ballerup DENMARK

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This leaflet was prepared in August 2004