

Daivobet® 50/500 gel

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.

Daivobet® 50/500 gel is the brand name. Daivobet® gel is a combination product. The generic names of the two active ingredients are calcipotriol and betamethasone dipropionate.

Keep this leaflet.

You may want to read it again.

What is in this leaflet?

This leaflet answers some common questions about using the medicine Daivobet® gel. 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® gel against the benefits it is expected to have for you.

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

What Daivobet® gel is used for

Daivobet® gel is used as topical treatment of body and scalp psoriasis. Psoriasis is a skin disorder in which skin cells are overactive. This causes redness, scaling and thickness of your skin. Daivobet® gel contains two active ingredients:

- calcipotriol (related to Vitamin D)

- betamethasone dipropionate (a corticosteroid).

The calcipotriol in Daivobet® gel treats the overactive skin cells. The betamethasone dipropionate relieves redness, swelling, itching and irritation of the skin.

Daivobet® gel 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® gel

When you must not use Daivobet® gel

Do not use Daivobet® gel if you:

- are allergic to calcipotriol, betamethasone dipropionate or any of the other ingredients listed at the end of this leaflet (see **Product description**) or any other similar medicine, such as topical corticosteroids
- have high blood calcium levels (ask your doctor)
- have other types of psoriasis known as generalised pustular or erythrodermic exfoliative psoriasis (your doctor will identify these conditions for you)
- have serious liver or kidney disease.

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® gel on skin affected by:

- viral, fungal, bacterial or parasitic skin infections
- tuberculosis (TB) or syphilis
- perioral dermatitis (red rash around the mouth)
- thin skin, easily damaged skin, stretch marks
- ichthyosis (dry skin with fish like scales)
- acne
- rosacea
- ulcers or broken skin.

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

Do not use Daivobet® gel

- after the expiry date printed on the pack OR
- if it is 3 months after the bottle 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 the medicine to your pharmacist for disposal.

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

Before you start to use it

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

Tell your doctor if you

- are pregnant
- are breastfeeding
- intend to breastfeed.

Do not use Daivobet® gel in children.

Safety and effectiveness of Daivobet® gel 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 using 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® gel.

How to use Daivobet® gel

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 Daivobet® gel to use

Apply enough gel to completely cover the psoriasis plaques.

Usually an amount equal to 1 level teaspoon (4g) is enough to cover an area the size of the scalp or 2 elbows, 2 knees and both hands.

The area treated should not be more than 30% of the body surface area (BSA). (Note: this is approximately the area on one whole leg and one whole arm.) Discuss this with your doctor.

Do not use more than 15g in **one day (around 3½ teaspoons).**

For example, no more than half (½)

of a 30g bottle in one day or quarter (¼) of a 60g bottle.

Do not use more than 100g in **one week.**

For example, no more than 3 bottles of 30g in one week or no more than 1½ bottles of 60g in one week.

If you also use other calcipotriol containing products (e.g.: Daivobet® ointment, Daivonex®) on your body psoriasis, then the **total** amount of calcipotriol products must not exceed 15 grams per day or 100 grams per week and the total area treated should not exceed 30% of the total body surface.

NOTE: If you use more than the recommended amount of Daivobet® gel, 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® gel or any other product containing calcipotriol (e.g.: Daivobet® ointment, Daivonex®) should **not** be used until the calcium level has become normal again.

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

How to use Daivobet® gel

Apply Daivobet® gel only to areas affected by psoriasis.

Daivobet® gel should be applied on dry skin on the body and/or to the scalp when your hair is dry.

For Body Psoriasis

1. Shake the bottle before use and remove the cap.



2. Squeeze gel onto a clean finger.



3. Using the finger apply enough gel to completely cover the psoriasis plaque and gently rub in. You will need to repeat steps 2 and 3 until all of the affected areas are covered.



For best results leave on during the day or night. The treated area does not need to be covered. You may wear your usual clothes however avoid contact with fabric that is easily stained by grease (e.g. silk).

For Scalp Psoriasis

Washing your hair before application of Daivobet® gel is not necessary.

1. Comb the hair first to remove any loose scales (part your hair before you apply the gel). Shake the bottle before use and remove the cap.



2. Squeeze gel onto a clean finger.



3. Using the finger apply the gel to the areas of the scalp affected by psoriasis and gently rub in with your fingertips. You will need to repeat steps 2 and 3 until all of the affected areas are covered.



To get the best results, do **not** wash your hair immediately after applying the gel. Let the gel remain on the scalp for a few hours, such as overnight or during the day.

4. While your hair is still **dry** (prior to wetting your hair), rub a mild shampoo into the areas where the gel was applied.



5. Leave the shampoo on the scalp for a couple of minutes before washing.



6. Wash your hair as usual.



- Take care not to get the gel in your eyes. If this happens, rinse your eyes with clean water and tell your doctor.
- If you accidentally put some of the gel onto skin not affected by psoriasis, wipe it off as soon as possible.
- Do not bandage, tightly cover or wrap the treated area
- After applying the gel avoid contact with fabric that is easily stained by grease (e.g. silk).

Do not use Daivobet® gel

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

Wash your hands thoroughly after applying Daivobet® gel on any part of your body, unless your hands are the affected area being treated. Avoid spreading the gel to other parts of the body (especially the face, mouth and eyes).

Thoroughly wash your hands prior to handling infants or children.

If any skin irritation develops, **wash off the Daivobet® gel.**

When to use Daivobet® gel preparations

Apply Daivobet® gel **once a day** at the most convenient time for you. Apply at about the same time each day.

How long to use it

Each treatment course would normally last for up to four weeks for scalp psoriasis and up to eight weeks for psoriasis on the body.

Your doctor may decide to stop treatment with Daivobet® gel once your psoriasis has improved, and to recommence it as needed.

If you forget to use it

If you forget to use Daivobet® gel, use it as soon as you remember, then continue as before. **Do not** use an increased dose of the gel to make up for the forgotten doses.

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 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® gel

Things you must do

While you are using Daivobet® gel, 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 outdoors.

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

If you become pregnant while using Daivobet® gel, tell your doctor immediately.

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

Your doctor may do blood tests whilst you are using Daivobet® gel (or any other product containing calcipotriol, for example Daivobet® ointment, 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® gel).

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

Side effects

As with all medicines, Daivobet® gel 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® gel**

or

- **if you notice any of the following and they worry you:**
 - skin irritation (including itching, redness, burning, dryness, pain, swelling or peeling)
 - a rash on your face or body
 - a change in the colour of your skin
 - your skin is more sensitive to light
 - change in control of diabetes.

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® gel

Keep Daivobet® gel in the box until required.

Storage

Keep Daivobet® gel in a cool dry place, store below 25°C. Do not refrigerate.

Keep the bottle in the box to protect from light.

Keep Daivobet® gel 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® gel that is left over if:

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

Product description

What it looks like

Daivobet® gel is an almost clear, colourless to slightly off-white gel.

Daivobet® gel is available as 15 g (starter pack), 30 g and 60 g bottles. Please note, not all pack sizes are marketed.

Ingredients

Daivobet® gel contains the active ingredients:

- calcipotriol (50 microgram/g)
- betamethasone dipropionate (500 microgram/g).

It also contains:

- paraffin, liquid
- polyoxypropylene-11 stearyl ether
- dl-alpha-tocopherol
- castor oil, hydrogenated
- butylhydroxytoluene (E321).

The Australian Registration Number is AUST R 161936.

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

Supplier

Daivobet® gel is supplied in Australia by:

LEO Pharma Pty Ltd,
Level 3, Tower 1,
25 Montpelier Road,
Bowen Hills, QLD 4006,
AUSTRALIA

Australia Toll free no: 1800 991 778

Daivobet® gel is supplied in New Zealand by:

LEO Pharma Ltd
Level 31, Vero Centre,
48 Shortland Street,
Auckland 1010,
New Zealand Toll Free No:
0800 497 456

Daivobet® gel is manufactured by:

LEO Laboratories Ltd (LEO Pharma)
Dublin, IRELAND

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