

Calcipotriol/Betamethasone Sandoz® 50/500

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Calcipotriol/Betamethasone Sandoz?

Calcipotriol/Betamethasone Sandoz contains the active ingredients calcipotriol and betamethasone (as dipropionate). Calcipotriol/Betamethasone Sandoz is used to treat a skin condition called psoriasis.

For more information, see Section [1. Why am I using Calcipotriol/Betamethasone Sandoz?](#) in the full CMI.

2. What should I know before I use Calcipotriol/Betamethasone Sandoz?

Do not use if you have ever had an allergic reaction to calcipotriol, betamethasone, or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Calcipotriol/Betamethasone Sandoz?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Calcipotriol/Betamethasone Sandoz and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Calcipotriol/Betamethasone Sandoz?

- Apply Calcipotriol/Betamethasone Sandoz once a day (either morning or night), unless otherwise directed by your doctor.
- Apply enough ointment to completely cover the psoriasis plaques.

More instructions can be found in Section [4. How do I use Calcipotriol/Betamethasone Sandoz?](#) in the full CMI.

5. What should I know while using Calcipotriol/Betamethasone Sandoz?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Calcipotriol/Betamethasone Sandoz.• Protect the treated skin areas from sunlight and Ultra Violet (UV) rays.• If you become pregnant while using Calcipotriol/Betamethasone Sandoz, tell your doctor immediately.
Things you should not do	<ul style="list-style-type: none">• 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.• Do not use other topical corticosteroids (e.g. Advantan®, Diprosone®, Elocon®) on areas treated with Calcipotriol/Betamethasone Sandoz.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how Calcipotriol/Betamethasone Sandoz affects you.
Looking after your medicine	<ul style="list-style-type: none">• Keep your Calcipotriol/Betamethasone Sandoz in a cool dry place where the temperature stays below 25°C.• However, do not keep Calcipotriol/Betamethasone Sandoz in the refrigerator, as the ointment will not spread easily.

For more information, see Section [5. What should I know while using Calcipotriol/Betamethasone Sandoz?](#) in the full CMI.

6. Are there any side effects?

Tell your doctor or pharmacist if you have any unpleasant effects while you are using Calcipotriol/Betamethasone Sandoz or if you notice any of the following and they worry you: skin irritation, skin peeling, itching, skin burning sensation, skin shrinkage or wasting, rash on your face or body, worsening of psoriasis, infected hair roots, bruising of skin, skin pain, change in the colour of your skin, your skin is more sensitive to light, headache, back pain, change in control of diabetes mellitus.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Calcipotriol/Betamethasone Sandoz®

50/500

Active ingredient(s): *calcipotriol, betamethasone (as dipropionate)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Calcipotriol/Betamethasone Sandoz. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Calcipotriol/Betamethasone Sandoz.**

Where to find information in this leaflet:

- [1. Why am I using Calcipotriol/Betamethasone Sandoz?](#)
- [2. What should I know before I use Calcipotriol/Betamethasone Sandoz?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Calcipotriol/Betamethasone Sandoz?](#)
- [5. What should I know while using Calcipotriol/Betamethasone Sandoz?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Calcipotriol/Betamethasone Sandoz?

Calcipotriol/Betamethasone Sandoz contains the active ingredients calcipotriol and betamethasone (as dipropionate). Calcipotriol is related to Vitamin D and treats the overactive skin cells. Betamethasone is a corticosteroid and relieves redness, swelling, itching and irritation of the skin..

Calcipotriol/Betamethasone Sandoz is used to treat a skin condition called psoriasis.

Calcipotriol/Betamethasone Sandoz is used only on skin affected by plaque-type psoriasis.

Psoriasis is a skin disorder in which skin cells are overactive. Calcipotriol/Betamethasone Sandoz 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.

2. What should I know before I use Calcipotriol/Betamethasone Sandoz?

Warnings

Do not use Calcipotriol/Betamethasone Sandoz if:

- you are allergic to calcipotriol, betamethasone, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

- you are allergic to any other similar medicine, such as topical corticosteroids.
- you have severe widespread psoriasis, generalised pustular psoriasis, or erythrodermic exfoliative psoriasis (your doctor will identify these conditions for you)
- you have high blood calcium levels
- you are taking calcium supplements, drugs to treat calcium deficiency, vitamin D supplements or vitamin D-like medicines, for example calcitriol
- you have kidney or liver problems
- you have any viral, fungal or bacterial skin infections
- you have tuberculosis (TB) or syphilis
- you have perioral dermatitis (red rash around the mouth)
- you have thin skin, easily damaged skin, stretch marks
- you have ichthyosis (dry skin with fish like scales)
- you have acne
- you have rosacea
- you have ulcers or broken skin.

Do not use Calcipotriol/Betamethasone Sandoz:

- after the expiry date printed on the pack
- if it is 12 months after the tube was first opened
- if the packaging is torn, doesn't look quite right or shows signs of tampering.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Do not breastfeed if you are using Calcipotriol/Betamethasone Sandoz ointment on your breasts.

Use in children

Do not use Calcipotriol/Betamethasone Sandoz in children.

Safety and effectiveness of Calcipotriol/Betamethasone Sandoz in those below 18 years of age has not been established.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or

supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Tell your doctor if you are taking calcium supplements, drugs to treat calcium deficiency, vitamin D supplements or vitamin D-like medicines, for example calcitriol. Do not use Calcipotriol/Betamethasone Sandoz if you are taking these.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Calcipotriol/Betamethasone Sandoz.

4. How do I use Calcipotriol/Betamethasone Sandoz?

How much to use

- Apply enough ointment to completely cover the psoriasis plaques.
- One fingertip unit (FTU) is enough to cover an area of skin twice the size of your palm. For example, if the area to be treated is 2 elbows and 2 knees, you may require up to 4 FTU's of ointment.
- One fingertip unit (FTU) is the amount of ointment, squeezed out of a tube, from the tip of an adult's index finger to the first crease in the finger.
- 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.
- If you use other calcipotriol containing products on your body psoriasis, then the total amount of calcipotriol products must not exceed 15 g per day or 100 g 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 Calcipotriol/Betamethasone Sandoz, 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 Calcipotriol/Betamethasone Sandoz or any other product containing calcipotriol (e.g.; Daivonex®) should not be used until the calcium level has become normal again.

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

When to use Calcipotriol/Betamethasone Sandoz

- Apply Calcipotriol/Betamethasone Sandoz once a day (either morning or night), unless otherwise directed by your doctor.

How to use Calcipotriol/Betamethasone Sandoz

NOTE: unlike certain other skin preparations, which you use very sparingly, use Calcipotriol/Betamethasone Sandoz as follows:

- Apply Calcipotriol/Betamethasone Sandoz only to the psoriasis plaques in a thin layer 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 Calcipotriol/Betamethasone Sandoz:

- 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 Calcipotriol/Betamethasone Sandoz on any part of your body, unless your hands are being treated.**
 - Thoroughly wash your hands prior to handling infants or children.
 - Take care not to get Calcipotriol/Betamethasone Sandoz in your eyes. If this happens, rinse your eyes with clean water and tell your doctor.
 - Avoid getting Calcipotriol/Betamethasone Sandoz on your face, scalp, mouth or eyes accidentally (see above).
 - If any skin irritation develops, wash off the Calcipotriol/Betamethasone Sandoz.

How long to use Calcipotriol/Betamethasone Sandoz

- Continue to use Calcipotriol/Betamethasone Sandoz for as long as your doctor tells you. Each treatment course would normally last for up to four weeks.
- Your doctor may decide to stop Calcipotriol/Betamethasone Sandoz treatment once your psoriasis has improved, and to recommence it as needed.

If you forget to use Calcipotriol/Betamethasone Sandoz

Calcipotriol/Betamethasone Sandoz should be used regularly at the same time each day. If you miss your dose at the usual time, 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 Calcipotriol/Betamethasone Sandoz

If you think that you have used too much Calcipotriol/Betamethasone Sandoz, you may need urgent medical attention.

You should immediately:

- phone the Australian Poisons Information Centre (by calling **13 11 26**), or the New Zealand National Poisons Information Centre (by calling **0800 POISONS** or **0800 764 766**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Calcipotriol/Betamethasone Sandoz?

Things you should do

- While you are using Calcipotriol/Betamethasone Sandoz, 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 Calcipotriol/Betamethasone Sandoz.**
- **If you become pregnant while using Calcipotriol/Betamethasone Sandoz, 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 Calcipotriol/Betamethasone Sandoz (or any other product containing calcipotriol). These tests check the levels of calcium in your blood and how well your kidneys are working ("renal function").

Remind any doctor, dentist or pharmacist you visit that you are using Calcipotriol/Betamethasone Sandoz.

Things you should 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 Section 4. [How do I use Calcipotriol/Betamethasone Sandoz?](#)).**
- Do not use other topical corticosteroids (e.g. Advantan®, Diprosone®, Elocon®) on areas treated with Calcipotriol/Betamethasone Sandoz.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Calcipotriol/Betamethasone Sandoz affects you.

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

Looking after your medicine

- Keep your Calcipotriol/Betamethasone Sandoz in a cool dry place where the temperature stays below 25°C.

- However, do not keep Calcipotriol/Betamethasone Sandoz in the refrigerator, as the ointment will not spread easily.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

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

When to discard your medicine

Ask your pharmacist what to do with any Calcipotriol/Betamethasone Sandoz that is left over if:

- your doctor tells you to stop using Calcipotriol/Betamethasone Sandoz
- the tube has been opened for more than 12 months
- the expiry date has passed.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Skin-related:</p> <ul style="list-style-type: none">• skin irritation• skin peeling• itching• skin burning sensation• skin shrinkage or wasting• rash on your face or body• worsening of psoriasis• infected hair roots• bruising of skin• skin pain• change in the colour of your skin• your skin is more sensitive to light <p>Other:</p> <ul style="list-style-type: none">• headache• back pain	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
Blood sugar-related: <ul style="list-style-type: none">change in control of diabetes mellitus	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems or to Medsafe at <https://pophealth.my.site.com/carmreportnz/s/>. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Calcipotriol/Betamethasone Sandoz contains

Active ingredient (main ingredient)	calcipotriol (50 microgram/g) betamethasone dipropionate (500 microgram/g).
Other ingredients (inactive ingredients)	liquid paraffin oleyl alcohol alpha-tocopherol white soft paraffin

Do not take this medicine if you are allergic to any of these ingredients.

What Calcipotriol/Betamethasone Sandoz looks like

Calcipotriol/Betamethasone Sandoz 50/500 – off-white ointment. Available in a tube of 30 grams (AUST R 255532).

Who distributes Calcipotriol/Betamethasone Sandoz

Calcipotriol/Betamethasone Sandoz is distributed in Australia by:

Sandoz Pty Ltd
100 Pacific Highway
North Sydney, NSW 2060
Australia
Tel 1800 726 369

Calcipotriol/Betamethasone Sandoz is distributed in New Zealand by:

Sandoz New Zealand Limited
12 Madden Street
Auckland 1010
New Zealand
Tel 0800 726 369

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