

Actobet 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 Actobet 50/500 gel?

Actobet 50/500 gel contains the active ingredients calcipotriol monohydrate and betamethasone dipropionate. Actobet 50/500 gel is used to treat body and scalp psoriasis.

For more information, see Section [1. Why am I using Actobet 50/500 gel?](#) in the full CMI.

2. What should I know before I use Actobet 50/500 gel?

Do not use if you have ever had an allergic reaction to calcipotriol monohydrate and betamethasone dipropionate 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 Actobet 50/500 gel?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Actobet 50/500 gel 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 Actobet 50/500 gel?

- Actobet 50/500 gel is for topical use (on the skin). Actobet 50/500 gel is designed for direct application to your skin (on the body or scalp), where it is affected by psoriasis.

More instructions can be found in Section [4. How do I use Actobet 50/500 gel?](#) in the full CMI.

5. What should I know while using Actobet 50/500 gel?

| | |
|------------------------------------|--|
| Things you should do | <ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Actobet 50/500 gel.• Protect the treated skin areas from sunlight and Ultraviolet (UV) rays.• Keep all appointments with your doctor as they may do blood tests to check calcium levels whilst you are using Actobet 50/500 gel. |
| Things you should not do | <ul style="list-style-type: none">• Except for psoriasis, do not use Actobet 50/500 gel on skin affected by viral, bacterial or parasitic infections and other skin diseases.• Do not use more than the recommended daily or weekly dose.• Do not use other topical corticosteroids on areas treated with Actobet 50/500 gel. |
| Looking after your medicine | <ul style="list-style-type: none">• Store it in a cool dry place below 25°C away from moisture, heat or sunlight.• Do not refrigerate. |

For more information, see Section [5. What should I know while using Actobet 50/500 gel?](#) in the full CMI.

6. Are there any side effects?

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The most common side effects include skin irritation, rash on your face or body. Serious potential side effects are symptoms of an allergic reaction, such as difficulty breathing, swelling of the face, lips or tongue, hives, rash or itching.

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.

Actobet 50/500

Active ingredient(s): *Calcipotriol and Betamethasone*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Actobet 50/500 gel. **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 Actobet 50/500 gel.**

Where to find information in this leaflet:

- [1. Why am I using Actobet 50/500 gel?](#)
- [2. What should I know before I use Actobet 50/500 gel?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Actobet 50/500 gel?](#)
- [5. What should I know while using Actobet 50/500 gel?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Actobet 50/500 gel?

Actobet 50/500 gel contains the active ingredients **calcipotriol monohydrate (related to vitamin D) and betamethasone dipropionate (a corticosteroid).**

Actobet 50/500 gel is used as a 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.

The calcipotriol in Actobet 50/500 gel treats the overactive skin cells. The betamethasone dipropionate relieves redness, swelling, itching and irritation of the skin.

2. What should I know before I use Actobet 50/500 gel?

Warnings

Do not use Actobet 50/500 gel if:

- you are allergic to calcipotriol, betamethasone dipropionate, 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 have high blood calcium levels (ask your doctor)
- you have other types of psoriasis known as generalised pustular, guttate, erythrodermic or exfoliative psoriasis (your doctor will identify these conditions for you).
- you have 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 Actobet 50/500 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

Do not use Actobet 50/500 gel:

- on large areas of damaged skin
- in skin folds (e.g. 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)

If any of these apply, return the medicine to your pharmacist for disposal.

If you are not sure whether you should start using Actobet 50/500 gel, talk to your doctor.

Check with your doctor if you:

- are suffering from any illness before using Actobet 50/500 gel
- take any medicines for any other condition
- have a known allergy to Actobet 50/500 gel, calcipotriol, betamethasone dipropionate or any of the ingredients listed at the end of this leaflet.

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 use Actobet 50/500 gel in children.

Safety and effectiveness of Actobet 50/500 gel 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.

Some medicines may interfere with Actobet 50/500 gel and affect how it works.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Actobet 50/500 gel.

4. How do I use Actobet 50/500 gel?

How much to use

- Apply enough gel to completely cover the psoriasis plaques.
- Usually an amount equal to 1 level teaspoon (4 g) 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 15 g in one day (around 3½ teaspoons). For example, no more than half (½) of a 30 g tube in one day or quarter (¼) of a 60 g tube.
- Do not use more than 100 g in one week. For example, no more than 3 tubes of 30 g in one week or no more than 1½ tubes of 60 g in one week.
- If you also use other calcipotriol containing products on your body for 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.
- Follow the instructions provided and use Actobet 50/500 gel until your doctor tells you to stop.

When to use Actobet 50/500 gel

- Actobet 50/500 gel should be used **once a day** at the most convenient time for you. Apply at about the same time each day.
- 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 Actobet 50/500 gel once your psoriasis has improved, and to recommence it as needed.

How to use Actobet 50/500 gel

Apply Actobet 50/500 gel only to areas affected by psoriasis.

Actobet 50/500 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 tube 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:

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

Wash your hands thoroughly after applying Actobet 50/500 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 Actobet 50/500 gel.**

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 Actobet 50/500 gel once your psoriasis has improved, and to recommence it as needed.

If you forget to use Actobet 50/500 gel

Actobet 50/500 gel 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 continue as before.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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

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 Actobet 50/500 gel

If you use more than the recommended amount of Actobet 50/500 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 Actobet 50/500 gel or any other product containing calcipotriol should not be used until the calcium level has become normal again.

Blood calcium levels will quickly normalise when your doctor discontinues Actobet 50/500 gel treatment.

If you think that you have used too much Actobet 50/500 gel, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), 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 Actobet 50/500 gel?

Things you should do

While you are using Actobet 50/500 gel, protect the treated skin areas from sunlight and Ultraviolet (UV) rays, for example, by wearing protective clothing. This is particularly important if your job or lifestyle means you spend time outdoors.

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

Your doctor may do blood tests whilst you are using Actobet 50/500 gel (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”).

Call your doctor straight away if you:

- If you become pregnant while using Actobet 50/500 gel

Remind any doctor, dentist or pharmacist you visit that you are using Actobet 50/500 gel.

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.
- Do not use other topical corticosteroids on areas treated with Actobet 50/500 gel.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Actobet 50/500 gel affects you.

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

This medicine is not addictive.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly. Do not refrigerate.

Store it in a cool dry place below 25°C 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.

When to discard your medicine

Ask your pharmacist what to do with any Actobet 50/500 gel that is left over if:

- your doctor tells you to stop using Actobet 50/500 gel, or
- the tube has been opened for more than 6 months or
- 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.

Tell your doctor or pharmacist if you have any unpleasant effects while you are using Actobet 50/500 gel.

Less serious side effects

| Less serious side effects | What to do |
|--|---|
| <p>Skin-related:</p> <ul style="list-style-type: none"> • skin irritation (including flaking, itching, dry skin, redness, swelling or peeling) • skin pain • burning sensation on skin • a rash on your face or body • a change in the colour of your skin • your skin is more sensitive to light • skin infection • acne • stretch marks • infected hair follicles • hair loss or thinning • worsening of psoriasis <p>Eye-related:</p> <ul style="list-style-type: none"> • eye irritation <p>Other:</p> | <p>Speak to your doctor if you have any of these possible side effects and they worry you.</p> |

| | |
|---|--|
| <ul style="list-style-type: none"> change in control of diabetes | |
|---|--|

Serious side effects

| Serious side effects | What to do |
|--|---|
| Symptoms of a severe allergic reaction (anaphylaxis), including difficulty breathing, swelling of the face, lips, tongue or other parts of the body, hives, rash or itching of the skin. | 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. 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 Actobet 50/500 gel contains

| | |
|---|---|
| Active ingredients (main ingredients) | calcipotriol [as monohydrate] (50 microgram/g) betamethasone [as dipropionate] (500 microgram/g) |
| Other ingredients (inactive ingredients) | liquid paraffin polyoxypropylene-11 stearyl ether hydrogenated castor oil |
| Potential allergens | polyoxypropylene-11 stearyl ether contains butylated hydroxytoluene hydrogenated castor oil contains peanut products and tocopherols |

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

What Actobet 50/500 gel looks like

Actobet 50/500 gel is an almost clear, colourless to slightly off -white gel.

Actobet 50/500 gel is available as 30 g tubes and 60 g tubes (AUST R 419553).

Who distributes Actobet 50/500 gel

Actor Pharmaceuticals Pty Ltd

Level 6, 50 Berry Street

North Sydney NSW 2060

Australia

Telephone: 1800 322 690

www.actorpharma.com.au

This leaflet was prepared in July 2025.