

Glenbex[®] Foam Spray

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 Glenbex[®] ?

Glenbex[®] contains the active ingredients calcipotriol monohydrate and betamethasone dipropionate. Glenbex[®] is used to treat Psoriasis.

For more information, see Section [1. Why am I using Glenbex[®]?](#) in the full CMI.

2. What should I know before I use Glenbex[®] ?

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 Glenbex[®]?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Glenbex[®] 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 Glenbex[®]?

- Glenbex[®] is for topical use (on the skin). Glenbex[®] is designed for direct application (spray on) to your skin, where it is affected by psoriasis.

More instructions can be found in Section [4. How do I use Glenbex[®]?](#) in the full CMI.

5. What should I know while using Glenbex[®] ?

| | |
|-----------------------------|--|
| Things you should do | <ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are using Glenbex[®]. |
| Things you should not do | <ul style="list-style-type: none">Do not stop using this medicine suddenly. Except for psoriasis, do not use Glenbex[®] on skin affected by viral, bacterial or parasitic infections and other skin diseases. |
| Looking after your medicine | <ul style="list-style-type: none">Extremely flammable Pressurised container: May burst if heated. Protect from sunlight and do not expose to temperatures above 50°C. Do not pierce or burn, even after use. Do not spray on an open flame or other ignition source. Keep away from sparks, open flames and other ignition sources. Do not smoke while applying Glenbex[®]. |

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

6. Are there any side effects?

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

Some side effects include skin irritation, rash on your face or body.

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.

Glenbex[®] Foam Spray

Calcipotriol 50 micrograms/gram presented as monohydrate and Betamethasone 500 microgram/gram presented as dipropionate

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

Consumer Medicine Information (CMI)

This leaflet provides important information about using Glenbex[®]. **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 Glenbex[®].**

Where to find information in this leaflet:

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

1. Why am I using Glenbex[®]?

Glenbex[®] is a combination product, contains the active ingredients calcipotriol monohydrate and betamethasone dipropionate.

Glenbex[®] is an antipsoriatic medicine for topical use.

Glenbex[®] is used to treat psoriasis.

Psoriasis is a skin disorder in which skin cells are overactive. This causes redness, scaling and thickness of your skin. Glenbex[®] contains two active ingredients:

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

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

Glenbex[®] is available only with a doctor's prescription.

2. What should I know before I use Glenbex[®]?

Warnings

Do not use Glenbex[®] if:

- you are allergic to calcipotriol monohydrate, betamethasone dipropionate, or any of the ingredients listed at the end of this leaflet or any other similar medicine, such as topical corticosteroids.
- 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 or erythrodermic exfoliative psoriasis (your doctor will identify these conditions for you).

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 Glenbex[®] on skin affected by:

- viral, fungal, bacterial or parasitic skin infections
- tuberculosis (TB) 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 Glenbex[®].

Do not use Glenbex[®]

- after the expiry date printed on the pack OR
- if the can has been opened for more than 6 months 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 Glenbex[®], talk to your doctor.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition
- are pregnant
- are breast-feeding
- intend to breast feed.

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 Glenbex® in children.

Safety and effectiveness of Glenbex® 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.

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.

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Glenbex®.

4. How do I use Glenbex®?

Caution: Extremely flammable. Please read important information under 'Storage'.

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.

Glenbex® is for topical use (on the skin). Before use, read the patient information, even if you have used Glenbex® before. Glenbex® is designed for direct application (spray on) to your skin, where it is affected by psoriasis.

How much to take / use

- As a guide on how much Glenbex® to use: A short 2 second spray of Glenbex® provides 0.5g of the medication and this amount should be sufficient to cover an area of skin roughly corresponding to the area of an adult hand.
- Do not use more than 15g in one day. 15g corresponds to the amount sprayed from the can when the actuator is fully pressed down for 1 minute. Do not use more than 100g in one week. For example, no more than 2 cans in one week. One 60g can should last you at least 4 days.
- If you also use other calcipotriol containing products (e.g.: Daivobet® gel or ointment, Daivonex®) for your psoriasis, then the total amount of calcipotriol products must not exceed 15g per day or 100 grams per week.
- Follow the instructions provided and use Glenbex® until your doctor tells you to stop.

When to take / use Glenbex®

- Apply Glenbex® once a day at the most convenient time for you, trying to applying it about the same time

of the day each day (for example, morning, afternoon or evening).

How to use Glenbex®

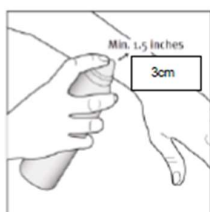
Glenbex® should be applied to dry skin on the affected areas of the body or scalp.

For body psoriasis

- Shake the can for a few seconds before use and remove the cap.



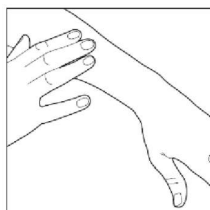
- Apply the medication by holding the can at least 3cm (approximately 1.5 inches) from the skin and spray onto the affected area.



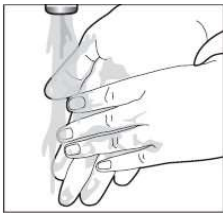
- The foam can be sprayed by holding the can in any orientation except horizontally. Apply a layer of foam only to the psoriasis plaques. Spray directly onto each affected skin area and gently rub in. If you accidentally put some of the foam on normal skin, wipe it off as soon as possible.



- Gently rub the foam into your affected skin areas. You will need to repeat steps 1 to 4 until all of the affected areas are covered.



- After applying your medication, put the cap back on the can to prevent accidental pressing of the can when not in use.
- Wash your hands well after using Glenbex® (unless you are using the foam to treat your hands). This will avoid accidentally spreading the foam to other parts of your body (especially face, mouth and eyes).



7. Take care not to get the foam spray in your eyes. If this happens, rinse your eyes with clean water and seek medical advice.
8. If you accidentally put some of the foam onto skin not affected by psoriasis, wipe it off as soon as possible.
9. Do not bandage, tightly cover or wrap the treated area

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 to remove any loose scales.
2. Shake the can for a few seconds before use and remove the cap.



3. Hold the can at least 3 cm (1.5 inches) away. Spray directly into the palm of your hand. The foam can be sprayed holding the can in any orientation except horizontally.



4. Scoop the foam onto your finger and apply it directly to the affected areas of the scalp. Minimize applying into the hair to make it easier to wash it out. Gently rub the foam into the scalp.



5. After applying your medication, put the cap back on the can to prevent accidental pressing of the can when not in use
6. Wash your hands well after using Glenbex®. This will avoid accidentally spreading the foam to other parts of your body (especially the face, mouth and eyes).



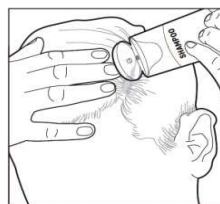
7. Take care not to get the foam in your eyes. If this happens, rinse your eyes with clean water and tell your doctor
8. If you accidentally put some of the foam onto skin not affected by psoriasis, wipe it off as soon as possible
9. Do not bandage, tightly cover or wrap the treated area

For best results, do not wash your hair immediately after applying. Leave Glenbex® on during the day or night. The treated area does not need to be covered.

After applying to the scalp, the following instructions when washing your hair, might be useful.

1. Apply a mild, non-medicated shampoo to the dry hair, focusing on the areas where the foam was applied.

It is easier to remove Glenbex® when the shampoo is applied to dry hair as water dilutes the cleansing effect of the shampoo.



2. Massage the shampoo into the dry hair/scalp. Leave the shampoo on the scalp for a couple of minutes before washing.
3. Rinse thoroughly with water.
4. Repeat normal shampooing if necessary.
 - 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 Glenbex® on any part of your body, unless your hands are being treated.

Thoroughly wash your hands prior to handling infants or children.

If any skin irritation develops, wash off the Glenbex®.

How long to use it

Each treatment course would normally last for up to four weeks.

Your doctor may decide to stop treatment with Glenbex® once your psoriasis has improved, and to recommence it as needed. Your doctor may decide on a different treatment period and/or repeated treatment.

If you forget to use Glenbex®

Glenbex® 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. Do not use an increased dose of the foam to make up for the forgotten doses.

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 use too much Glenbex®

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

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

If you think that you have used too much Glenbex®, 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 Glenbex®?

Things you should do

While you are using Glenbex®, 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.

Call your doctor straight away if you:

- have any unpleasant effects while you are using Glenbex®.

Remind any doctor, dentist or pharmacist you visit that you are using Glenbex®.

Things you should not do

- Do not stop using this medicine suddenly.

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

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

- Your doctor may do blood tests whilst you are using Glenbex® (or any other product containing calcipotriol, for example Daivobet® gel or ointment, Daivonex®). These tests check the levels of calcium in your blood and how well your kidneys are working (“renal function”).

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Glenbex® affects you.

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

This medicine is not addictive.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Keep Glenbex® in the box until required.
- Keep Glenbex® in a cool dry place, store below 25°C.

CAUTION: Extremely flammable Pressurised container: May burst if heated. Protect from sunlight and do not expose to temperatures above 50°C. Do not pierce or burn, even after use. Do not spray on an open flame or other ignition source. Keep away from sparks, open flames and other ignition sources. Do not smoke while applying Glenbex®.

Keep Glenbex® in the box to protect from light.

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 Glenbex® 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 Glenbex® that is left over if:

- your doctor tells you to stop using Glenbex®, or
- the can 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 Glenbex®.

Possible side effects

| Possible side effects | What to do |
|---|---------------------------------------|
| <ul style="list-style-type: none">• skin irritation (including itching, redness, dryness, swelling or peeling)• skin pain (including burning)• 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 |

Glenbex® contains butylated hydroxytoluene. This may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

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 Glenbex® contains

| | |
|--------------------------|---|
| Active ingredient | <ul style="list-style-type: none">• calcipotriol (50 microgram/g) [as monohydrate]• betamethasone dipropionate (500 microgram/g). |
| Other ingredients | <ul style="list-style-type: none">• liquid paraffin• polyoxypropylene-11 stearyl ether• isopropyl alcohol• dl-alpha-tocopherol• white soft paraffin• butylated hydroxytoluene• Propellants: propane, butane and isobutane |

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

What Glenbex® looks like

Glenbex® is in a pressurised can. After spraying, a white to off-white foam is formed on the skin. The foam is a non-expanding foam, which gradually collapses after spraying.

The Australian Registration number is AUST R 386430.

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

Who distributes Glenbex®

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