

EBGLYSS®

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.

- ▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using EBGLYSS?

EBGLYSS contains the active ingredient lebrikizumab. EBGLYSS is used to treat adult and adolescent patients (12 years of age and older) with moderate to severe atopic dermatitis (also known as atopic eczema).

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

2. What should I know before I use EBGLYSS?

Do not use if you have ever had an allergic reaction to lebrikizumab 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 EBGLYSS?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with EBGLYSS 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 EBGLYSS?

The EBGLYSS autoinjector should be injected under the skin every 2 weeks or every 4 weeks. Your doctor will tell you how much to use. Carefully follow the instructions on how to inject under the skin. Change your injection site each time.

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

5. What should I know while using EBGLYSS?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist
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	<p>you visit that you are using EBGLYSS.</p> <ul style="list-style-type: none">• Always follow your doctor's instructions carefully.• Use each EBGLYSS autoinjector (pre-filled pen) for single use only.• Tell your doctor if you are scheduled to receive any vaccinations. You should not receive a live vaccine if you are treated with EBGLYSS.
Things you should not do	<ul style="list-style-type: none">• Do not use in children under 12 years or in adolescents (12 to 18 years) weighing less than 40 kg.• Do not stop using this medicine suddenly without first checking with your doctor.• Do not use EBGLYSS if it is cloudy, discoloured, has visible particles or passed its expiration date.• Do not use EBGLYSS if you think it has been

	frozen or exposed to excessive heat.
Looking after your medicine	<ul style="list-style-type: none"> • Store refrigerated at 2°C to 8°C in the original carton to protect from light. Do not freeze. Do not expose to extreme heat. Do not shake. • Remove from the refrigerator at least 45 minutes before your injection. • If needed, EBGLYSS can be kept at room temperature up to 30°C for a maximum of 7 days. Once stored out of refrigeration, do not place back in the refrigerator.

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

6. Are there any side effects?

Common side effects include injection site reactions, eye infection, dry eyes, eye pain, blurry vision, sensitivity to light and eye and eyelid inflammation (including redness, swelling and itching). Other side effects include shingles infection and an increase in white blood cell count. 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.

- ▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information.
- You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

EBGLYSS®

Active ingredient: *lebrikizumab*

Consumer Medicine Information (CMI)

This leaflet provides important information about using EBGLYSS. **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 EBGLYSS.**

Where to find information in this leaflet:

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

1. Why am I using EBGLYSS?

EBGLYSS contains the active ingredient lebrikizumab. EBGLYSS belongs to a type of medicines called monoclonal antibodies and works by blocking a specific protein called interleukin-13 (IL-13). This protein contributes to inflammation and plays a role in atopic dermatitis.

EBGLYSS is used for the treatment of adult and adolescent patients (12 years of age and older) with moderate to severe atopic dermatitis (also known as atopic eczema).

2. What should I know before I use EBGLYSS?

Warnings

Do not use EBGLYSS if:

- You are allergic to lebrikizumab, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- The product appears cloudy, discoloured or contains particles, or the medicine has passed its expiration date or if it appears damaged.

Check with your doctor if you:

- have a parasitic (helminth) infection.
- have any other medical conditions, including any new or worsening eye problems, such as eye pain or changes in vision.
- take or use any medicines for any other condition, including topical or inhaled corticosteroid medicines.

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?](#)

Vaccination

- Make sure you are up to date with all vaccinations before starting EBGLYSS.
- Tell your doctor if you are scheduled for any vaccines or have recently been vaccinated. Some vaccines should not be given while you are taking EBGLYSS. Check with your doctor before receiving any vaccines.

Use in children and adolescents

Do not use EBGLYSS in children under 12 years or in adolescents (aged 12 to 18 years) who weigh less than 40 kg.

Pregnancy and breastfeeding

Tell your doctor if you are pregnant or intend to become pregnant. The effects of this medicine in pregnant women are not known. As a precautionary measure, avoid the use of EBGLYSS during pregnancy unless your doctor advises you to use it.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known if EBGLYSS passes into your breastmilk. You and your doctor should decide if you will breastfeed or use EBGLYSS. You should not do both.

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.

You should not receive certain types of vaccines while using EBGLYSS. Tell your doctor if you have recently received a vaccine or planned to receive a vaccine.

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

4. How do I use EBGLYSS?

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

Read the EBGLYSS “Instructions for Use” provided in the carton carefully before using EBGLYSS. If you do not understand the instructions, ask your doctor or pharmacist for help.

EBGLYSS is given as an injection under your skin, known as subcutaneous injection.

EBGLYSS is supplied as a 250 mg/2 mL single-dose autoinjector (pre-filled pen).

How much to use and when to use EBGLYSS

- Use the dose your doctor prescribes for you.
- Use EBGLYSS until your doctor tells you to stop.
- The recommended starting dose of EBGLYSS is:
First dose (considered as Week 0): **two (2)** 250 mg autoinjectors (pre-filled pens) injected under the skin (subcutaneously).
Then at Week 2: **two (2)** 250 mg autoinjectors (pre-filled pens) injected under the skin (subcutaneously).
Then from Week 4 up to Week 16: **one (1)** 250 mg autoinjector (pre-filled pen) injected under the skin (subcutaneously) every 2 weeks.
- After completing the starting dose, and if you have had an adequate response, your doctor may prescribe the maintenance dose. The recommended maintenance dose is:
From Week 16 onwards: **one (1)** 250 mg autoinjector (pre-filled pen) injected under the skin (subcutaneously) every 4 weeks.

- If you did not have an adequate response to the starting dose, your doctor may recommend that you either:
 - continue with **one (1)** 250 mg autoinjector (pre-filled pen) injected under the skin (subcutaneously) every 2 weeks until Week 24 and then decide if you can continue with the maintenance dose, or
 - stop taking EBGLYSS.

How to use EBGLYSS

- **Read the "Instructions for Use" provided within the carton carefully before using EBGLYSS.**
- Do not use EBGLYSS if it is cloudy, discoloured, has visible particles or is past its expiration date.
- In adult patients, the injection can be self-administered or given by another person or caregiver, after proper training in injection technique.
- In adolescents under the 18 years of age, EBGLYSS should be given by an adult, after training in injection technique.
- EBGLYSS should be removed from the refrigerator at least 45 minutes before your injection so that it reaches room temperature.
- EBGLYSS should be injected under the skin (subcutaneously) of your stomach or upper leg:

Stomach area (abdomen) —

At least 5 centimetres (2 inches) away from the belly button (navel).

Front of thigh —

At least 5 centimetres (2 inches) above the knee and 5 centimetres (2 inches) below the groin.

- If you would like to inject into the back of your upper arm, request another person or a caregiver (after training in injection technique) to inject your dose.
- For each injection, you should inject the whole contents of the single use autoinjector (pre-filled pen).
- Do not inject in the exact same spot every time.
- Do not inject in an area where the skin is tender, bruised, red, hard, or into an area of skin that is affected by eczema (atopic dermatitis) or skin lesions.

If you forget to use EBGLYSS

If you miss your dose at the usual time, inject the missed dose as soon as possible. Then take your next dose at your regular scheduled time. If you have any questions about your schedule, ask doctor or pharmacist.

If you use too much EBGLYSS

If you think that you have used too much EBGLYSS, 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 EBGLYSS?

Things you should do

- Always follow your doctor's instructions carefully.
- Tell your doctor if you are scheduled to receive any vaccinations. You should not receive a live vaccine if you are treated with EBGLYSS.
- Use each EBGLYSS pen for single use only.
- Tell your doctor and pharmacist before you start any new medicine that you are using EBGLYSS.
- Remind any doctor, dentist or pharmacist you visit that you are using EBGLYSS.

Things you should not do

- Do not stop using this medicine suddenly and without checking with your doctor.
- Do not use EBGLYSS if it is cloudy, discoloured, has visible particles or is past its expiration date.
- Do not use if the autoinjector (pre-filled pen) is damaged or if you are not sure that it is working properly.
- Do not use EBGLYSS if you think it has been frozen or exposed to excessive heat (temperatures above 30°C).

- Do not give your EBGLYSS to anyone else, even if they have the same condition as you. Your doctor has prescribed EBGLYSS only for you.

Driving or using machines

EBGLYSS is unlikely to influence your ability to drive or use machines.

Looking after your medicine

- Before use, keep your EBGLYSS autoinjectors (pre-filled pens) in a refrigerator where the temperature is between 2°C-8°C. If needed, EBGLYSS may be kept at room temperature up to 30°C for a maximum of 7 days. Once stored out of refrigeration, do not place EBGLYSS back in the refrigerator.
- Keep EBGLYSS in the original carton to protect from light.
- Do not allow your EBGLYSS autoinjector (pre-filled pen) to freeze. Throw away if frozen.
- Do not allow your EBGLYSS autoinjector (pre-filled pen) to be exposed to excessive heat greater than 30°C.
- Do not shake your EBGLYSS autoinjector (pre-filled pen).
- Discard any unused portion (see Section [When and how to dispose of your medicine](#))

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

Keep EBGLYSS where young children cannot reach it.

When and how to dispose of your medicine

After injecting EBGLYSS, immediately dispose the used autoinjector (pre-filled pen) in a sharps disposal container as instructed by your doctor or pharmacist.

After removal from the refrigerator, EBGLYSS must be used within 7 days or disposed.

Do not dispose of EBGLYSS in your household rubbish.

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>Eye-related:</p> <ul style="list-style-type: none">• eye infection• redness of eyes• eye dryness• itchy and watery eye(s)• eye pain• blurry vision• sensitivity to light• eye and eyelid inflammation (including redness, swelling and itching) <p>Injection site reactions:</p> <ul style="list-style-type: none">• redness, swelling or itching at the injection site	<p>Speak to your doctor if you have any of these less serious side effects and they worry you or are persistent and do not go away.</p>

Serious side effects

Serious side effects	What to do
<p>Hypersensitivity reactions:</p>	<p>Tell your doctor if you have any of these serious side effects</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● breathing problems or wheezing ● swelling of the face, lips, mouth, tongue, or throat ● hives ● itching ● fainting, dizziness, feeling lightheaded ● skin rash ● cramps in your stomach area (abdomen). <p>Symptoms of shingles, such as:</p> <ul style="list-style-type: none"> ● headache ● sensitivity to light ● tingling ● itching or painful skin rash with blisters. <p>Blood related:</p> <ul style="list-style-type: none"> ● increase in white blood cell count, which may be found during blood tests 	<p>as they may require medical attention.</p>

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 EBGLYSS contains

Active ingredient (main ingredient)	lebrikizumab
Other ingredients (inactive ingredients)	Histidine Glacial acetic acid Sucrose Polysorbate 20 Water for injections

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

What EBGLYSS looks like

EBGLYSS is a clear to opalescent, colourless to slightly yellow to slightly brown solution, free of visible particles, available as a single use autoinjector (prefilled pen).

(Aust R 406290)

Who distributes EBGLYSS

Eli Lilly Australia Pty Ltd

Level 9, 60 Margaret Street

Sydney, NSW 2000

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If you have any questions about EBGLYSS, contact Eli Lilly at 1800 454 559 (Australia) or your healthcare professional for assistance.

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