

# EBGLYSS 250 MG SOLUTION FOR INJECTION IN PRE-FILLED PEN

Lebrikizumab 250 mg

## What is in this leaflet

1. What Ebglyss is used for
2. How Ebglyss works
3. Before you use Ebglyss
4. How to use Ebglyss
5. While you are using it
6. Side effects
7. Storage and Disposal of Ebglyss
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of RiMUP revision

## What Ebglyss is used for

Ebglyss is used to treat adults and adolescents 12 years and older with a body weight of at least 40 kg with moderate-to-severe atopic dermatitis, also known as atopic eczema, who can be treated with systemic treatments (a medicine given by mouth or injection).

Ebglyss may be used with eczema medicines that you apply to the skin or it may be used on its own.

## How Ebglyss works

Ebglyss contains the active substance lebrikizumab.

Lebrikizumab is a monoclonal antibody (a type of protein) that blocks the action of another protein called interleukin-13. Interleukin-13 plays a major role in causing the symptoms of atopic dermatitis. By blocking interleukin-13, Ebglyss can improve your atopic dermatitis and reduce the related itching and skin pain.

## Before you use Ebglyss

### - When you must not use it

Do not take Ebglyss if:

- if you are allergic to lebrikizumab or any of the other ingredients of this medicine (listed in Product Description).

If you think you may be allergic, or you are not sure, ask your doctor,

pharmacist or nurse for advice before using Ebglyss.

### - Before you start to use it

Talk to your doctor, pharmacist or nurse before using Ebglyss.

### *Vaccination*

Talk to your doctor regarding your current vaccinations plan. See section 'Taking other medicines'.

### *Children and adolescents*

This medicine should not be used in children with atopic dermatitis below the age of 12 or adolescents 12 to 17 years of age and weighing less than 40 kg because it has not been tested in this age group.

### *Pregnancy and lactation*

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

The effects of this medicine in pregnant women are not known. It is better to avoid the use of Ebglyss during pregnancy unless your doctor advises you to use it.

It is not known whether lebrikizumab can pass into breast milk. If you are breast-feeding or are planning to breast-feed, talk to your doctor before using this medicine. You and your doctor should decide if you will breast-feed or use Ebglyss. You should not do both.

### - Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Tell your doctor or pharmacist:

- if you are using, have recently used or might use any other medicines
- if you have recently had a vaccination or plan to have one.

You should not be given certain types of vaccines (live vaccines) while using Ebglyss.

## How to use Ebglyss

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

### - How much to use

Your doctor will decide how much Ebglyss you need.

The recommended dose is:

- Two initial injections of 250 mg lebrikizumab each (500 mg in total) at week 0 and week 2.
- One injection with 250 mg once every two weeks from week 4 up to week 16. Based on how you respond to the medicine, your doctor may decide to stop giving the medicine or to keep giving you one 250 mg injection every other week up to week 24.
- One injection with 250 mg every four weeks from week 16 onwards (maintenance dosing).

Ebglyss is given as an injection under your skin (subcutaneous injection) into the thigh or abdomen, except for 5 cm around the navel. If somebody else gives the injection, it can also be given into the upper arm. You and your doctor or nurse will decide if you can inject Ebglyss yourself.

It is recommended that you change the injection site with each injection.

Ebglyss should not be injected into skin that is tender, damaged or has bruises or scars, or in an area of skin that is affected by atopic dermatitis or other skin lesions. For the initial 500 mg dose, administer two 250 mg injections consecutively in different injection sites.

It is important not to try to inject yourself until you have been trained by your doctor or nurse. A caregiver may also give you your Ebglyss injection

after proper training. In adolescents 12 years of age and older, it is recommended that Ebglyss is administered by or under the supervision of an adult.

The pre-filled pen must not be shaken.

Read the “Instructions for use” for the pre-filled pen carefully before using Ebglyss.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Your doctor will decide how long you will use it for.

- If you forget to use it

If you have forgotten to inject a dose of Ebglyss, talk to your doctor, pharmacist or nurse.

If you forgot to inject Ebglyss when you usually have planned to do it, take it as soon as you remember. The next dose should be injected on the regular scheduled day.

- If you use too much (overdose)

If you took more Ebglyss than your doctor prescribed or you took the dose before it was scheduled, talk to your doctor, pharmacist or nurse.

**While you are using Ebglyss**

- Things you must do

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Every time you get a new pack of Ebglyss, it is important that you note down the date and the batch number (which is on the packaging after “Lot”) and keep this information in a safe place.

Tell all the doctors, dentists and pharmacists treating you that you are using Ebglyss.

Tell your doctor immediately if you become pregnant while using this medication.

Take Ebglyss only with a doctor’s prescription.

- Things you must not do

Do not stop using Ebglyss without speaking to your doctor first.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

Do not use any new medicines without consulting your doctor or pharmacist.

Do not give Ebglyss to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

Ebglyss is unlikely to influence your ability to drive and use machines.

Allergic reactions

Very rarely, this medicine can cause allergic (hypersensitivity) reactions. These reactions can occur shortly after you take Ebglyss, but also may happen later. If you notice symptoms of an allergic reaction, you should stop using this medicine and contact your doctor or get medical help immediately. Signs of an allergic reaction include:

- breathing problems
- swelling of the face, mouth, and tongue
- fainting
- dizziness
- feeling lightheaded (because of low blood pressure)
- hives, itching and skin rash

Eye problems

Talk to your doctor if you have any new or worsening eye problems, including redness and discomfort in the eye, eye pain or changes in vision.

**Side effects**

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

**Common** (may affect up to 1 in 10 people)

- Redness and discomfort in the eye (conjunctivitis)

- Inflammation of the eye due to an allergic reaction (conjunctivitis allergic)
- Eye dryness
- Injection site reactions

**Uncommon** (may affect up to 1 in 100 people)

- Shingles, a painful, blistering rash in one part of the body (herpes zoster)
- Increase in eosinophils (a type of white blood cell; eosinophilia)
- Inflammation of the cornea (the transparent layer that covers the front of the eye; keratitis)
- Eyelid itching, redness and swelling (blepharitis)

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

**Storage and Disposal of Ebglyss**

- Storage

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C - 8°C). Do not freeze.

Store in the original package in order to protect from light.

Do not use this medicine if you notice that the solution is cloudy or discoloured or if it contains visible particles. Before use, remove the carton from the refrigerator, take the pre-filled pen out of the carton and allow to reach room temperature by waiting for 45 minutes. After removal from the refrigerator, Ebglyss must be stored below 30°C and used within 7 days or discarded. Once stored out of refrigeration, do not place back in the

---

refrigerator. The date of removal from the refrigerator may be recorded on the carton.

This medicine is for single use only.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

- sucrose
- polysorbate 20 (E432)
- water for injections

- MAL number:  
MAL\*\*\*\*\*

**Manufacturer**

Eli Lilly and Company  
Lilly Corporate Center  
Indianapolis, Indiana (IN)  
46285, United States (USA).

**Product Description**

- What it looks like

Ebglyss is a clear to opalescent, colourless to slightly yellow to slightly brown sterile solution for injection, free of visible particles.

It is supplied as carton packs containing one single-dose pre-filled pen.

- Ingredients

- Active ingredient

- lebrizumab

- Inactive ingredients

- histidine
- glacial acetic acid (E260)

**Product Registration Holder**

Zuellig Pharma Sdn. Bhd.  
No. 15, Persiaran Pasak Bumi,  
Seksyen U8, Perindustrian Bukit  
Jelutong,  
40150 Shah Alam, Selangor, Malaysia.

**Date of revision**

29/10/2025

**Serial Number**

NPRA (R3)25/101