

Package leaflet: Information for the user

Ebglyss 250 mg solution for injection in pre-filled pen lebrikizumab

▼ 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. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Ebglyss is and what it is used for
2. What you need to know before you use Ebglyss
3. How to use Ebglyss
4. Possible side effects
5. How to store Ebglyss
6. Contents of the pack and other information

Instructions for use

1. What Ebglyss is and what it is used for

Ebglyss contains the active substance lebrikizumab.

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.

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.

2. What you need to know before you use Ebglyss

Do not use Ebglyss

- if you are allergic to lebrikizumab or any of the other ingredients of this medicine (listed in section 6).

If you think you may be allergic, or you are not sure, ask your doctor, pharmacist or nurse for advice before using Ebglyss.

Warnings and precautions

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

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.

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.

Vaccination

Talk to your doctor regarding your current vaccinations plan. See section “Other medicines and Ebglyss”.

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.

Other medicines and Ebglyss

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.

Pregnancy, breast-feeding and fertility

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.

Driving and using machines

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

3. 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 Ebglyss is given and for how long

Your doctor will decide how much Ebglyss you need and how long you will use it for.

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.

If you use more Ebglyss than you should

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.

If you forget to use Ebglyss

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 stop using Ebglyss

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.

4. Possible 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)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for the MHRA Yellow card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ebglyss

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.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Ebglyss contains

- The active substance is lebrikizumab. Each pre-filled pen contains 250 mg of lebrikizumab in a 2 mL solution (125 mg/mL).
- The other ingredients are histidine, glacial acetic acid (E260), sucrose, polysorbate 20 (E432) and water for injections.

What Ebglyss looks like and contents of the pack

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 or 2 single-dose pre-filled pens, and as multipacks containing 3 single-dose pre-filled pens (3 packs of 1), 4 single-dose pre-filled pens (2 packs of 2), 5 single-dose pre-filled pens (5 packs of 1) or 6 single-dose pre-filled pens (3 packs of 2). Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Almirall, S.A.
Ronda General Mitre, 151
08022 Barcelona
Spain

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Ireland/United Kingdom (Northern Ireland)

Almirall, S.A.
Tel: +353 (0) 1431 9836

Great Britain

Almirall Limited
Tel: 0800 0087 399

This leaflet was last revised in: September 2023.

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:
<http://www.ema.europa.eu>

Instructions for use

These Instructions for use contain information on how to inject Ebglyss.

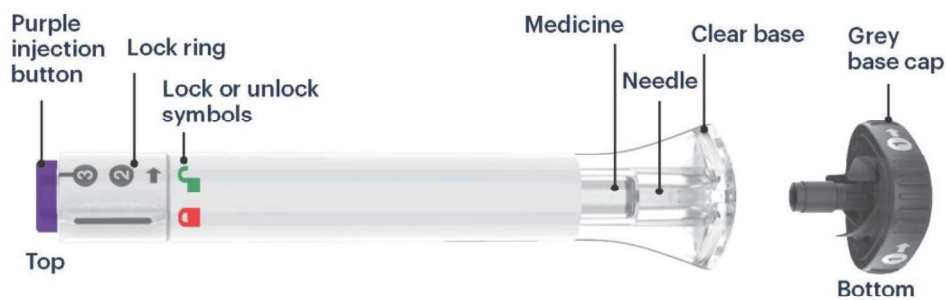
Read these “Instructions for use” before you use this medicine and carefully follow all the step-by-step instructions.



Important information you need to know before injecting Ebglyss

- Your healthcare provider should show you how to prepare and inject Ebglyss using the pre-filled pen. **Do not** inject yourself or someone else until you have been shown how to inject Ebglyss.
- Each Ebglyss pre-filled pen contains 1 dose of Ebglyss (250 mg). **The pre-filled pen is for one-time use only.**
- The Ebglyss pre-filled pen contains glass parts. Handle it carefully. If you drop it on a hard surface, **do not** use it. Use a new Ebglyss pre-filled pen for your injection.
- Your healthcare provider may help you decide where on your body to inject your dose. You can also read the **Choose and clean your injection site** section of these instructions to help you choose which area works best for you.
- If you have vision or hearing problems, **do not** use Ebglyss pre-filled pen without help from a caregiver.

Parts of the Ebglyss pre-filled pen



Preparing to inject Ebglyss

Prepare supplies:

- Ebglyss pre-filled pen from the refrigerator
- alcohol wipe
- cotton ball or piece of gauze
- sharps disposal container

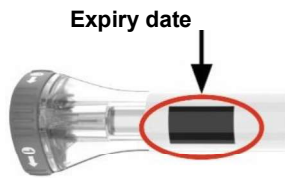
Wait 45 minutes

Remove the Ebglyss pre-filled pen from the carton with the grey base cap on and allow the pre-filled pen to warm up to room temperature for 45 minutes before injecting.

- **Do not** warm up the pre-filled pen with a microwave, or hot water, or direct sunlight.
- **Do not** use the pre-filled pen if the medicine is frozen.

Inspect the pre-filled pen and the medicine

Make sure you have the right medicine. The medicine inside should be clear. It may be colourless to slightly yellow to slightly brown.



Do not use the pre-filled pen (see **Disposing of Ebglyss pre-filled pen**) if the:

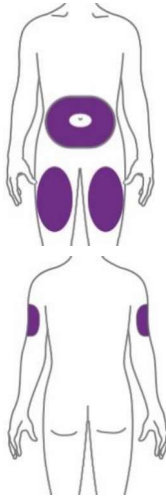
- Pen looks damaged
- medicine is cloudy, is discoloured, or contains particles
- expiry date printed on the label has passed

Wash your hands with soap and water

Choose and clean your injection site

Your healthcare provider can help you choose the injection site that is best for you.

Clean the injection site with an alcohol wipe and let dry.



You or another person may inject into these areas.

Another person should inject into this area.

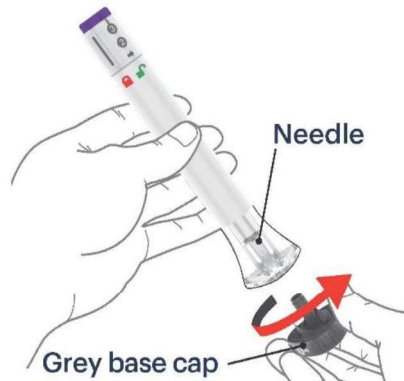
- **Stomach area (abdomen) —**
At least 5 cm (2 inches) away from the belly button (navel).
- **Front of thigh —**
At least 5 cm (2 inches) above the knee and 5 cm (2 inches) below the groin.
- **Back of upper arm —**
Another person should inject into the back of your upper arm.

Do not inject in the exact same spot every time.

Do not inject into areas where the skin is tender, bruised, red, hard or scarred, or in an area of skin that is affected by atopic dermatitis or other skin lesions.

Injecting Ebglyss

1 Uncap the pre-filled pen



- Make sure the pre-filled pen is **locked**.

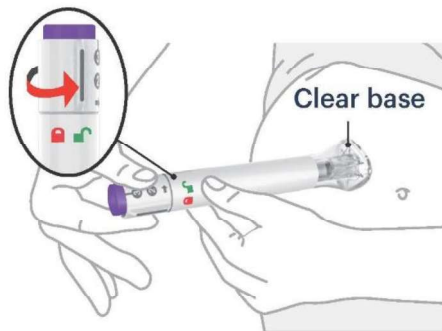


When you are ready to inject, twist off the grey base cap and throw it away in your household waste.

Do not put the grey base cap back on — this could damage the needle.

Do not touch the needle inside the clear base.

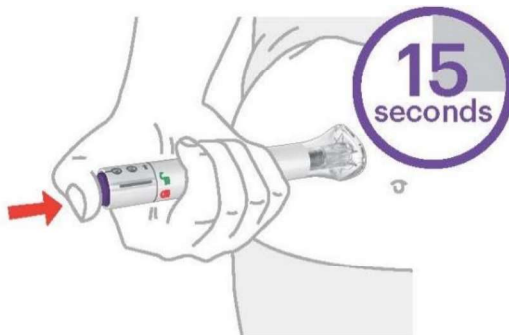
2 Place and unlock



Place and hold the clear base flat and firmly against the skin.

- Keep the clear base on the skin, then turn the lock ring to the **unlock** position.

3 Press and hold for 15 seconds



Press and hold the purple injection button and **listen** for two loud clicks:

- first click = injection started
- second click = injection completed

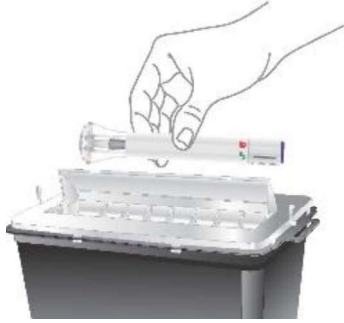
The injection may take up to 15 seconds.

You will know the injection is complete when the grey plunger is visible. Then remove the pre-filled pen from the injection site.



Disposing of Ebglyss pre-filled pen

Throw away the used pre-filled pen



Dispose of the used Ebglyss pre-filled pen in a sharps disposal container right away after use.

Do not throw away (dispose of) the Ebglyss pre-filled pen in your household waste.

If you do not have a sharps disposal container, you may use a household container that is:

- made of a heavy-duty plastic,
- can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
- upright and stable during use,
- leak-resistant, and
- properly labelled to warn of hazardous waste inside the container.

When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container.

There may be local laws about how you should throw away needles and syringes.

For more information about safe sharps disposal ask your healthcare provider about options available in your area.

Do not recycle your used sharps disposal container.

Commonly Asked Questions

Q. What if I see bubbles in the pre-filled pen?

A. Air bubbles are normal. They will not harm you or affect your dose.

Q. What if there is a drop of liquid on the tip of the needle when I remove the grey base cap?

A. A drop of liquid on the tip of the needle is normal. This will not harm you or affect your dose.

Q. What if I unlock the Pen and press the purple injection button before twisting off the grey base cap?

A. **Do not** remove the grey base cap. Throw away (dispose of) the pre-filled pen and use a new one.

Q. Do I need to hold the purple injection button down until the injection is complete?

A. You do not need to hold the purple injection button down, but it may help you keep the pre-filled pen steady and firm against your skin.

Q. What if the needle did not retract after my injection?

A. **Do not** touch the needle or replace the grey base cap. Store the pre-filled pen in a safe place to avoid an accidental needlestick.

Q. What if there is a drop of liquid or blood on my skin after my injection?

A. This is normal. Press a cotton ball or gauze over the injection site. **Do not** rub the injection site.

Q. How can I tell if my injection is complete?

A. After you press the purple injection button, you will hear 2 loud clicks. The second loud click tells you that your injection is complete. You will also see the grey plunger at the top of the clear base. The injection may take up to 15 seconds.

Q. What if I remove the pre-filled pen before the second loud click or before the grey plunger stops moving?

A. You may not have received your full dose. Do not give another injection. Call your healthcare provider for help.

Q. What if I heard more than 2 clicks during my injection — 2 loud clicks and 1 soft one. Did I get my complete injection?

A. Some people may hear a soft click right before the second loud click. That is the normal operation of the pre-filled pen. **Do not** remove the pre-filled pen from your skin until you hear the second loud click.

Read the full package leaflet for the pre-filled pen before using Ebglyss.