

## Package leaflet: Information for the user

### Ebglyss 250 mg solution for injection in pre-filled syringe 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 syringe must not be shaken.

Read the “Instructions for use” for the pre-filled syringe 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](http://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 syringe 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 syringe 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, glass, pre-filled syringe or 2 single-dose pre-filled syringes, and as multipacks containing 3 single-dose pre-filled syringes (3 packs of 1), 4 single-dose pre-filled syringes (2 packs of 2), 5 single-dose pre-filled syringes (5 packs of 1) or 6 single-dose pre-filled syringes (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**

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

### **Important information for the Ebglyss pre-filled syringe with needle safety device:**

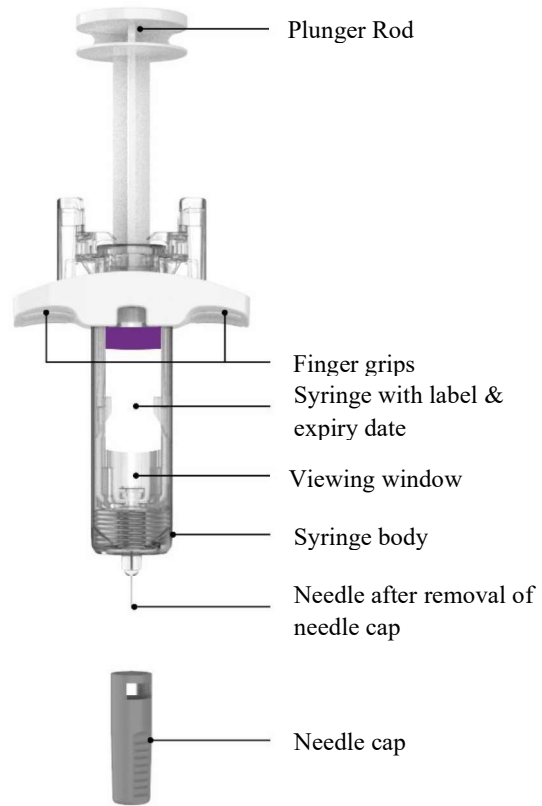
**Do not inject yourself or someone else until you have been shown by your healthcare professional how to inject Ebglyss.** Call your healthcare provider if you have any questions.

### **When using the Ebglyss pre-filled syringe**

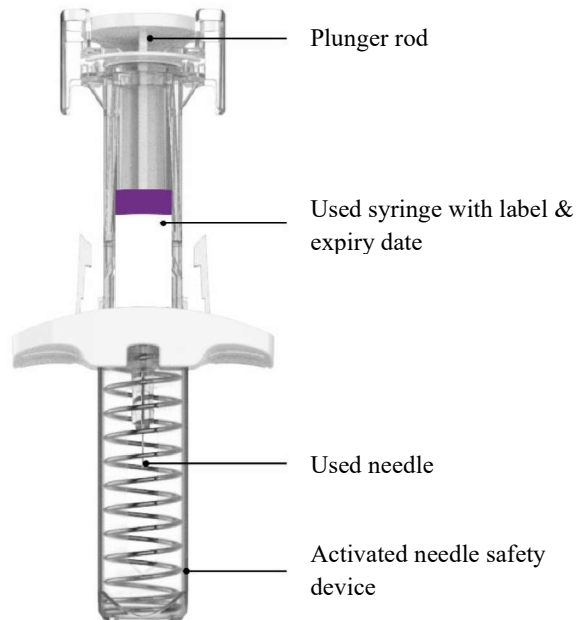
- Talk to your healthcare provider about how often you will need to inject the medicine.
- If you have vision problems, do not use Ebglyss pre-filled syringe without help from a caregiver.
- To reduce the risk of accidental needle sticks, each pre-filled syringe has a needle safety device that is automatically activated to cover the needle after your injection.
- Throw away (dispose of) your used Ebglyss single-dose pre-filled syringe immediately after use.
- **Do not** use Ebglyss pre-filled syringe if it has been dropped on a hard surface or damaged.
- **Do not** use Ebglyss pre-filled syringe if the needle cap is missing or not securely attached.
- **Do not** touch the plunger rod until you are ready to inject.
- **Do not** get rid of any air bubbles in the Ebglyss pre-filled syringe.
- **Do not** pull back on the plunger rod at any time.
- **Do not** inject through clothes.
- **Do not** remove the needle cap until right before you are ready to give the injection.
- **Do not re-use an Ebglyss single-dose pre-filled syringe.**

## Parts of the Ebglyss pre-filled syringe with needle safety device

### Before use

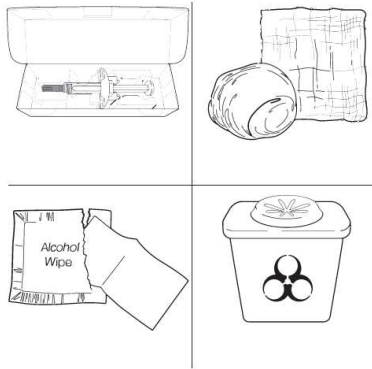


### After Use



## Preparing to inject Ebglyss

### Prepare supplies

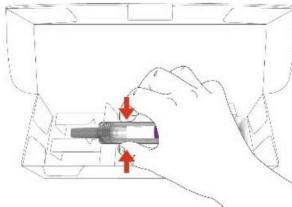


Make sure you have the following:

- 1 Ebglyss pre-filled syringe with needle safety device from the refrigerator
- 1 alcohol wipe\*
- 1 cotton ball or gauze\*
- 1 sharps disposal container\*

\*Items not included with the product.

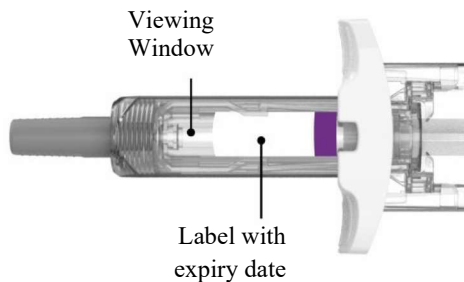
### Remove pre-filled syringe from carton



Remove the Ebglyss pre-filled syringe from the carton by holding the middle of the syringe body.

**Leave the needle cap on until you are ready to inject.**

### Inspect pre-filled syringe



When you receive your Ebglyss pre-filled syringes, **always check to see that you have the correct medicine and dose and visually inspect the pre-filled syringe.**

Note: You may gently rotate the plunger rod to view the syringe label.

**The label should read “Ebglyss”.**

**Do not use the Ebglyss pre-filled syringe if the expiry date has passed.**

**Do not use the Ebglyss pre-filled syringe if it has been damaged.**

Look at the medicine through the viewing window on the Ebglyss pre-filled syringe. The liquid should be clear, colourless to slightly yellow to slightly brown.

*Note: some air bubbles are normal.*

**Do not use the Ebglyss pre-filled syringe if the liquid is discoloured or cloudy, or it contains visible flakes or particles, or the syringe shows signs of damage, or the**



## Bring to room temperature



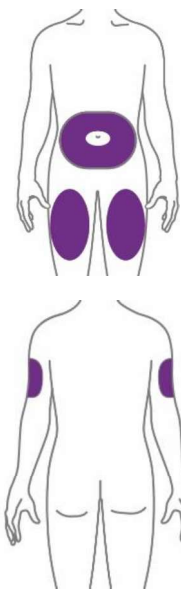
**syringe has been dropped, or the medicine is frozen.**

Place the Ebglyss pre-filled syringe on a flat surface and let it warm to room temperature naturally for at least 45 minutes.

**Do not heat the Ebglyss pre-filled syringe with a microwave or hot water.**

**Do not put the Ebglyss pre-filled syringe into direct sunlight.**

## Choose your injection site



You or another person may inject into these areas.

Another person should inject into this area.

- You can inject into your thigh or stomach area (abdomen), except for 5 cm (2 inches) around your belly button (navel).
- If you chose the front of your thigh, you should inject at least 5 cm (2 inches) above the knee and 5 cm (2 inches) below the groin.
- If you choose the outer area of the upper arm, you will need a caregiver to help you.
- Choose a different injection site each time you inject Ebglyss.

**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.

## Prepare your skin

Wash your hands with soap and water. Clean the injection site with an alcohol wipe. Let the injection site dry before injecting.

**Do not touch the injection site again or blow on it before the injection.**

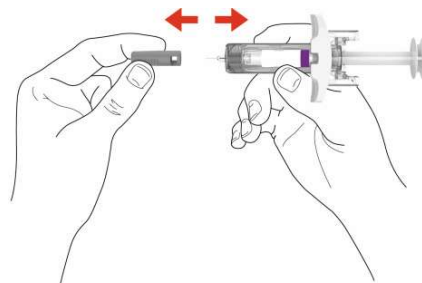
## Injecting Ebglyss

### 1 Remove needle cap

Hold the Ebglyss pre-filled syringe in the middle of the syringe body with the needle pointing away from you, and pull off the needle cap.

**Do not put the needle cap back on.**

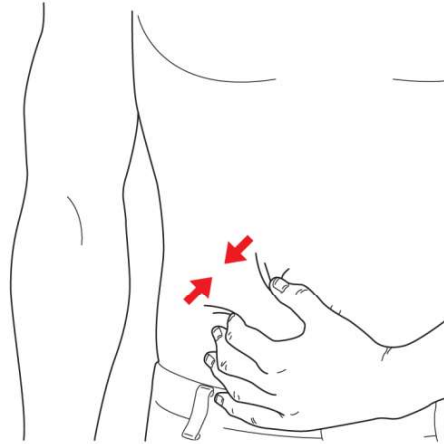
**Do not touch the needle.**



Inject your medicine immediately after removing the needle cap.

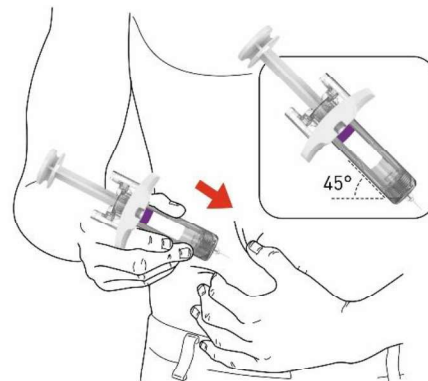
## 2 Pinch the injection site

Gently pinch a fold of skin at the injection site (thigh or stomach, except for 5 cm (2 inches) around your belly button, or outer area of the upper arm if injected by your caregiver).



## 3 Insert the needle

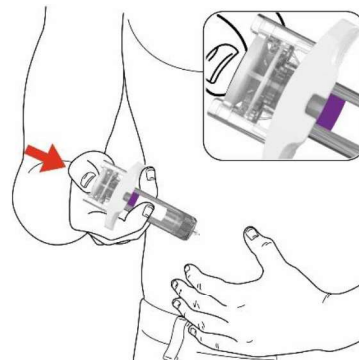
Insert the needle completely into the fold of skin at about a 45° angle.



## 4 Push in the plunger rod

Gently relax the pinch while keeping the needle in place. Slowly and steadily push the plunger rod down all the way until it stops and the pre-filled syringe is empty.

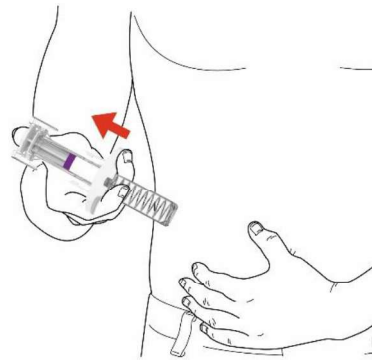
Note: It is normal to feel some resistance.



## 5 Release and remove

Lift your thumb to release the plunger rod until the needle is covered by the needle safety device, and then remove the pre-filled syringe from the injection site.

Lightly press a cotton ball or gauze on the injection site if you see any blood.  
**Do not put the needle cap back on.**  
**Do not rub your skin after injection.**



### Dispose of the pre-filled syringe safely

Put your used Ebglyss pre-filled syringe and needle cap in a sharps disposal container immediately after use.

**Do not dispose of (throw away) Ebglyss pre-filled syringes and needle caps 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,
- able to be closed with a tight-fitting, puncture resistant lid to keep sharps from falling 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, follow your community guidelines for the right way to dispose of it. There may be local laws regarding the disposal of used 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.

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