

**Patient Leaflet in Accordance with the Pharmacists' Regulations (Preparations) - 1986**

This medicine is dispensed with a physician's prescription only

## **Ebglyss**

### **Solution for injection in pre-filled pen**

#### **The active ingredient and its concentration:**

Each 1 ml contains 125 mg of lebrikizumab (lebrikizumab 125 mg/ml).

Each pre-filled pen contains 250 mg of lebrikizumab in 2 ml solution.

**Inactive ingredients and allergens in the preparation:** see chapter 6 "Additional Information".

**Read the entire leaflet carefully before using this medicine.** This leaflet contains concise information regarding this medicine. If you have any further questions, contact your doctor or pharmacist.

This medicine has been prescribed for the treatment of your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar.

### **1. WHAT IS THIS MEDICINE INTENDED FOR?**

Ebglyss is indicated for the treatment of moderate-to-severe atopic dermatitis in adults and adolescents 12 years and older with a body weight of at least 40 kg who are candidates for systemic therapy.

**Therapeutic group:** other dermatological preparations, agents for dermatitis, excluding corticosteroids.

Atopic dermatitis, also known as atopic eczema, 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.

Ebglyss contains the active substance lebrikizumab, 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. BEFORE USING THIS MEDICINE**

#### **Do not use this medicine if:**

- you are hypersensitive (allergic) to the active ingredient (lebrikizumab) or any of the other ingredients of this medicine (listed in chapter 6).

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

#### **Special warnings regarding the use of this medicine**

Talk to your doctor, pharmacist or nurse before using this medicine.

#### **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 “Drug interactions”.

#### **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 the efficacy and safety have not been tested in this age group.

#### **Drug interactions**

**If you are taking or have recently taken any other medicines, including nonprescription medications and nutritional supplements, tell your doctor or pharmacist.**

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**

##### Pregnancy

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.

##### Breast-feeding

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 has no or negligible influence on the ability to drive and use machines.

### **3. HOW TO USE THIS MEDICINE?**

Always use this medicine according to your doctor’s instructions. Check with your doctor or pharmacist if you are not sure about the dosage and manner of treatment with this medicine. The dosage and manner of treatment will be determined only by your doctor.

#### **The acceptable dosage of Ebglyss and for how long it is given**

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

#### **The acceptable dosage is usually:**

- An initial dose of 500 mg (two injections of 250 mg lebrikizumab each) at week 0 and also at week 2.

- Then, 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 two weeks up to week 24.
- Once an adequate response has been achieved, one injection with 250 mg every four weeks (maintenance dosing).

**Do not exceed the recommended dose.**

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 have accidentally taken a higher dose**

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 a child accidentally swallowed the medicine, contact your doctor or go to the hospital Emergency Room right away and bring the medicine pack with you.

**If you forget to use this medicine**

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 this medicine**

Do not stop using Ebglyss without speaking to your doctor first. Persist with the treatment as recommended by the doctor. Even if there is an improvement in your health, do not discontinue treatment with this medicine without consulting the doctor.

**Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.**

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

**4. SIDE EFFECTS**

Like all medicines, the use of Ebglyss can cause side effects in some users. Do not be alarmed while reading the list of side effects. You may not experience any of them.

**Allergic reactions**

Very rarely, this medicine can cause allergic (hypersensitivity) reactions. If you notice symptoms of an allergic reaction, you should stop using this medicine and contact your doctor or get medical help immediately. For further information see chapter 2.

### **Eye problems**

Talk to your doctor if you have any new or worsening eye problems. For further information see chapter 2.

**Common side effects** (may affect up to 1 in 10 users):

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

**Uncommon side effects** (may affect up to 1 in 100 users):

- 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)

**If a side effect has appeared, if one of the side effects worsens or if you suffer from a side effect not specified in the leaflet, you must consult the doctor.**

### **Reporting Side Effects**

Side effects can be reported to the Ministry of Health by clicking on the link “Reporting Side Effects due to Drug Treatment” that can be found on the Home Page of the Ministry of Health’s website ([www.health.gov.il](http://www.health.gov.il)), which refers to the online form for reporting side effects, or via the following link: <https://sideeffects.health.gov.il>

## **5. HOW TO STORE THIS MEDICINE?**

Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the sight and reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.

Do not use this medicine after the expiry date (exp. date) which is stated on the label and on the carton. The expiry date refers to the last day of that month.

### **Storage conditions:**

- Store in a refrigerator (2°C - 8°C). Do not freeze.
- Store in the original package in order to protect from light.
- 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 at a temperature up to 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.

Do not use this medicine if you notice that the solution is cloudy or discolored or if it contains visible particles.

This medicine is for single use only.

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

## **6. ADDITIONAL INFORMATION**

**In addition to the active ingredient, this medicine also contains:**

sucrose, L-histidine, glacial acetic acid, polysorbate 20, water for injection.

**What the medicine looks like and contents of the pack:**

Ebglyss is a clear to opalescent, colorless to slightly yellow to slightly brown sterile solution for injection, free of visible particles. It is supplied as a carton pack containing one single-dose pre-filled pen.

The pack size is 1 prefilled pen.

**Registration holder's name and address:** Eli Lilly Israel Ltd., 4 HaSheizaf St., P.O.Box 4246, Ra'anana 4366411.

**Manufacturer's name and address:** Eli Lilly & Company, Indianapolis, Indiana, USA.

Approved in November 2024.

**Drug registration number at the national medicine's registry of the Ministry of Health:**

177-68-38066-00

## Instructions for use

### Ebglyss solution for injection in pre-filled pen

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

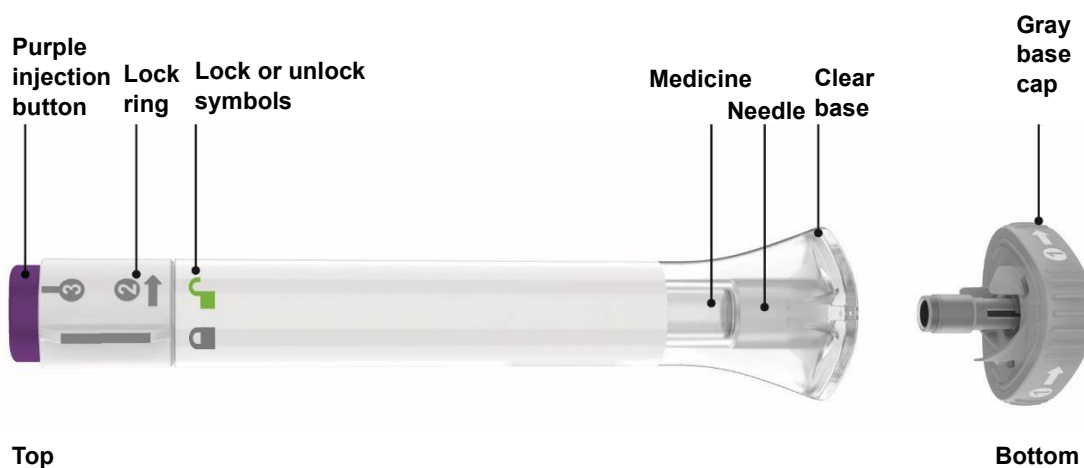
**Read these “Instructions for use” before you use this medicine and carefully follow all the step-by-step instructions.**



#### 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 pre-filled pen contains 1 dose of Ebglyss (250 mg). **The pen is for one-time use only.**
- The 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

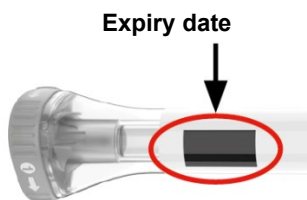
### Wait 45 minutes

Remove the Ebglyss pre-filled pen from the carton with the gray base cap on and allow the 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 pen and the medicine

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



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

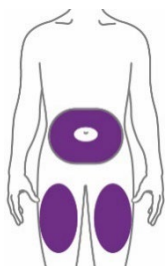
- Pen looks damaged
- medicine is cloudy, is discolored, or contains particles
- expiry date printed on the label has passed

### Wash your hands with soap and water

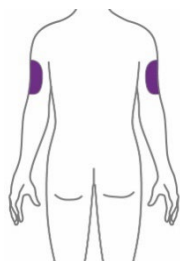
### Choose and clean your injection site

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 away from the belly button (navel).

- **Front of thigh -**

At least 5 cm above the knee and 5 cm below the groin.

- **Back of upper arm -**

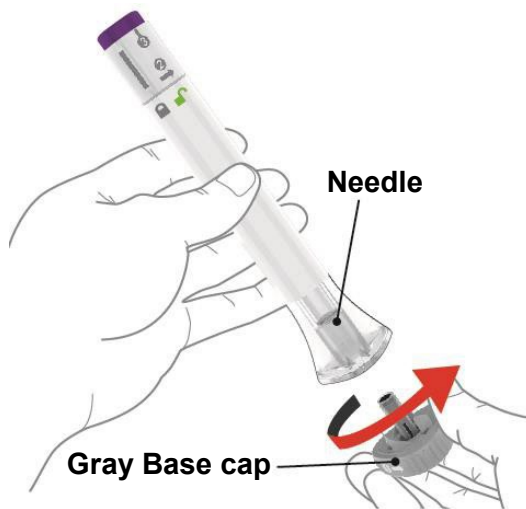
Another person should inject into the back of your upper arm.


**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 pen



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

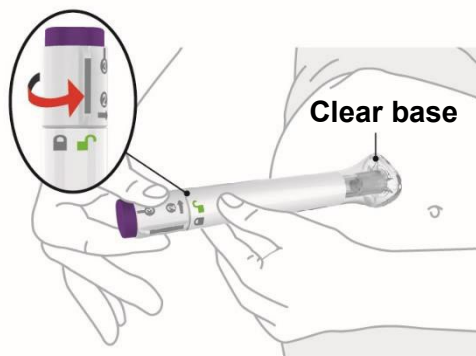



When you are ready to inject, twist off the gray base cap and throw it away in your household waste.

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

**Do not** touch the needle inside the clear base.

### 2 Place and unlock



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

### 3 Press and hold for 15 seconds



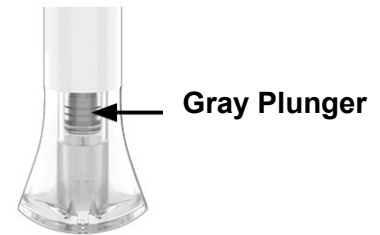
**Press and hold** the purple injection button and **listen** for two loud clicks:

- 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 gray 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.

Ask your healthcare provider how you should throw away needles and syringes.

For more information about safe sharps disposal ask your healthcare provider.

**Do not** recycle your used sharps disposal container.

### Commonly Asked Questions

**Q. What if I see bubbles in the 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 gray 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 gray base cap?**
- A. Do not** remove the gray 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 gray 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 gray 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 gray 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.**