

**PACKAGE LEAFLET**

## **Package leaflet: Information for the patient**

### **Elymbus 0.1 mg/g eye gel in single-dose container**

bimatoprost

**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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

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

#### **1. What Elymbus is and what it is used for**

Elymbus is an antiglaucoma preparation. It belongs to a group of medicines called prostamides.

Elymbus eye gel is used to reduce high pressure in the eye in adults. This medicine may be used on its own or with other drops called beta-blockers which also reduce pressure.

Your eye contains a clear, watery liquid that feeds the inside of the eye. Liquid is constantly being drained out of the eye and new liquid is made to replace this. If the liquid cannot drain out quickly enough, the pressure inside the eye builds up. This medicine works by increasing the amount of liquid that is drained. This reduces the pressure inside the eye. If the high pressure is not reduced, it could lead to a disease called glaucoma and eventually damage your sight.

#### **2. What you need to know before you use Elymbus**

##### **Do not use Elymbus**

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

##### **Warnings and precautions**

Talk to your doctor or pharmacist before using Elymbus.

Talk to your doctor, if:

- You have any breathing problems
- You have liver or kidney problems
- You have had a cataract surgery in the past
- You have or have had low blood pressure or low heart rate
- You have had a viral infection or inflammation of the eye

During treatment, Elymbus may cause a loss of fat around the eye, which may cause your eyelid crease to deepen, your eye to appear sunken (enophthalmos), your upper eyelid to droop (ptosis), the skin around your eye to tighten (involution of dermatochalasis) and the lower white part of your eye to

become more visible (inferior scleral show). The changes are typically mild, but if pronounced, they can affect your field of vision. The changes may disappear if you stop taking Elymbus. Elymbus may also cause your eyelashes to darken and grow, and cause the skin around the eyelid to darken too. The colour of your iris may also go darker. These changes may be permanent. The change may be more noticeable if you are only treating one eye.

### **Children and adolescents**

Elymbus has not been tested in children under the age of 18 and therefore should not be used by patients under 18 years.

### **Other medicines and Elymbus**

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines.

### **Pregnancy and breast-feeding**

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

Elymbus may get into breast milk so you should not breast-feed while you are taking Elymbus.

### **Driving and using machines**

Your sight may become blurred for a short time just after using Elymbus. You should not drive or use machines until your sight is clear again.

## **3. How to use Elymbus**

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

Elymbus should only be applied to the eye. The recommended dose is one drop of Elymbus in the evening, once daily in each eye that needs treatment.

If you use Elymbus with another eye medicine, it should be administered at least 15 minutes before Elymbus. Elymbus should be used last.

Do not use more than once a day as the effectiveness of treatment may be reduced.

### **Contact lens wearers**

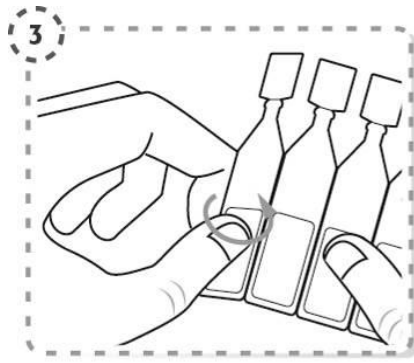
If you wear contact lenses, you should remove them before using Elymbus. After using Elymbus you should wait 15 minutes before putting your contact lenses back in.

### **Instructions for use**

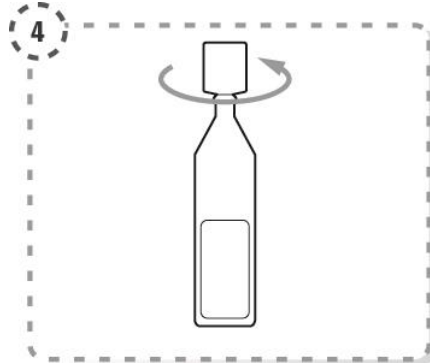
This medicine is intended to be administered into the eye.

Please follow these instructions to use the drops:

1. Wash your hands and sit or stand comfortably.
2. Open the sachet containing 10 single-dose containers.
3. Break off one single-dose container from the strip.



4. Twist open the top of the single-dose container as shown. Do not touch the tip after opening the container.



5. Use your finger to gently pull down the lower eyelid of your affected eye.
6. Tilt your head back and look at the ceiling.
7. Place the tip of the single-dose container close to, but not touching your eye.
8. Squeeze the single-dose container gently so that only one drop goes into your eye, then release the lower eyelid.



9. Repeat in your other eye if your doctor has told you to do this. Each single-dose container contains enough eye gel for both eyes.
10. Let go of the lower lid and close your eye(s) for a little while.
11. Wipe off any excess that runs down the cheek. If a drop misses your eye, try again.
12. Discard the single-dose container after use. Do not keep it to use it again. Since sterility cannot be maintained after the individual single-dose container is opened (preservative-free eye gel), a new container must be opened prior to each use.
13. Wipe away any extra liquid with a clean tissue.
14. Place the unopened single-dose containers back in the sachet. The unopened containers must be used within 1 month after opening the sachet.

**If you use more Elymbus than you should**

If you use more Elymbus than you should, it is unlikely to cause you any serious harm. Put your next dose in at the usual time. If you are worried, talk to your doctor or pharmacist.

#### **If you forget to use Elymbus**

If you forget to use Elymbus, use a single drop as soon as you remember, and then go back to your regular routine. Do not take a double dose to make up for a forgotten dose.

#### **If you stop using Elymbus**

Elymbus should be used every day to work properly. If you stop using Elymbus the pressure inside your eye may go up, therefore talk to your doctor before stopping this treatment.

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

## **4. Possible side effects**

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

The following side effects have been seen with Elymbus:

### **Common side effects**

These may affect up to 1 in 10 people

#### Affecting the eye

- Slight redness
- Eye pain
- Eye irritation
- Redness and discomfort in the eye
- A feeling that something is in your eye
- Dry eye
- Itchy eyes
- Temporary difficulty in seeing clearly

### **Uncommon side effects**

These may affect up to 1 in 100 people

#### Affecting the eye

- Small breaks in the surface of the eye, with or without inflammation
- Sensations like numbness, tingling, pins and needles in the eye
- Inflamed eyelids
- Loss of eyelashes
- Longer eyelashes
- Sensitivity to light
- Increasing tears
- Darker eyelashes
- Darker eyelid colour
- Swelling of the eyelid
- Itchy, red and dry skin on eyelids

#### Affecting the body

- Dizziness

The following side effects have been seen with bimatoprost eye drops solution (0.1 mg/ml, preserved formulation):

### **Very common side effects**

These may affect more than 1 in 10 people

#### Affecting the eye

- Slight redness (up to 29 % of people)
- Loss of fat in the eye region which can lead to deepening of your eyelid crease, sunken eye (enophthalmos), drooping eyelid (ptosis), tightening of the skin around your eye (involution of dermatochalasis), and the lower white part of your eye to become more visible (inferior scleral show)

### **Common side effects**

These may affect up to 1 in 10 people

#### Affecting the eye

- Small breaks in the surface of the eye, with or without inflammation
- Irritation
- Itchy eyes
- Longer eyelashes
- Irritation, when drop is put in the eye
- Eye pain

#### Affecting the skin

- Red and itchy eyelids
- Darker skin colour around the eye
- Hair growth around the eye

### **Uncommon side effects**

These may affect up to 1 in 100 people

#### Affecting the eye

- Darker iris colour
- Tired eye
- Swelling of the surface of the eye
- Blurred vision
- Loss of eyelashes

#### Affecting the skin

- Dry skin
- Crusting on the edge of the eyelid
- Swelling of the eyelid
- Itching

#### Affecting the body

- Headache
- Feeling of sickness

### **Side effects where the frequency is not known**

#### Affecting the eye

- Macular oedema (swelling of the retina at the back of the eye which may lead to worsening vision)
- Darker eyelid colour
- Dryness
- Sticky eyes
- A feeling that something is in your eye
- Swelling of the eye
- Increasing tears
- Ocular discomfort
- Sensitivity to light

#### Affecting the body

- Asthma

- Worsening of asthma
- Worsening of the lung disease called chronic obstructive pulmonary disease (COPD)
- Shortness of breath
- Symptoms of allergic reaction (swelling, redness of the eye and rash of the skin)
- Dizziness
- Increased blood pressure
- Skin discoloration (periocular)

In addition to the above side effects, the following side effects have been seen with another medicine containing a higher strength of bimatoprost eye drops solution (0.3 mg/ml, preserved formulation):

- Ocular burning
- An allergic reaction in the eye
- Inflamed eyelids
- Difficulty in seeing clearly
- Worsening of vision
- Swelling of the see-through layer that covers the eye
- Tears
- Darker eyelashes
- Retinal bleeding
- Inflammation within the eye
- Cystoid macular oedema (swelling of the retina within the eye leading to worsening vision)
- Eyelid twitching
- Eyelid shrinking, moving away from surface of the eye
- Skin redness around the eye
- Weakness
- An increase in blood-test results that show how your liver is working

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRAs Pharmacovigilance Website: [www.hpra.ie](http://www.hpra.ie)

By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Elymbus**

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 carton, sachet and single-dose container after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions.

**After first opening of the sachet:** use the single-dose containers within 1 month.

To help you remember, write down the date you opened the sachet.

Keep the unused single-dose containers in the opened sachet in order to protect them from light.

**After first opening of the single-dose container:** use immediately and discard the single-dose container after use.

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 Elymbus contains**

- The active substance is bimatoprost. Each g of eye gel contains 0.1 mg bimatoprost.
- The other ingredients are sorbitol, carbomer, sodium acetate trihydrate, macrogol, sodium hydroxide (for pH-adjustment), water for injections.

**What Elymbus looks like and contents of the pack**

Elymbus is a colourless opalescent eye gel in single-dose container. It is presented in single-dose containers packed in a sachet of 10 units.

Each single-dose container holds 0.3 g of product.

A pack size contains 10, 30 (3 x 10) or 90 (9 x 10) single-dose containers.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder**

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or

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**This medicine is authorised in the Member States of the European Economic Area under the following names:**

Austria, Belgium, Bulgaria, Cyprus, Croatia, Czech Republic, Denmark, Estonia, Finland, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, The Netherlands, Norway, Poland, Portugal, Romania, Slovenia, Slovakia, Spain, Sweden..... Elymbus  
France.....Elumibus

**This leaflet was last revised in May 2023.**

If you would like any more information, or would like the leaflet in a different format, please contact Medical Information at THEA Pharma Ltd, telephone number +44 (0) 345 521 1290.