

## Package leaflet: Information for the user

### Latanoprost/Timolol Zentiva 50 micrograms/ml + 5 mg/ml eye drops, solution

#### latanoprost/timolol

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

#### **1. What Latanoprost/Timolol Zentiva is and what it is used for**

Latanoprost/Timolol Zentiva contains two medicines: latanoprost and timolol. Latanoprost belongs to a group of medicines known as prostaglandin analogues. Timolol belongs to a group of medicines known as beta-blockers. Latanoprost works by increasing the natural outflow of fluid from the eye into the bloodstream. Timolol works by slowing the formation of fluid in the eye.

Latanoprost/Timolol Zentiva is used to reduce the pressure in your eye if you have conditions known as open angle glaucoma or ocular hypertension. Both these conditions are linked to an increase in the pressure within your eye, eventually affecting your eyesight. Your doctor will usually prescribe you Latanoprost/Timolol Zentiva when other medicines have not worked adequately.

#### **2. What you need to know before you use Latanoprost/Timolol Zentiva**

Latanoprost/Timolol Zentiva can be used in adult men and women (including the elderly), but is not recommended for use if you are less than 18 years of age.

##### **Do not use Latanoprost/Timolol Zentiva if you**

- are allergic to active substances latanoprost or timolol, beta-blockers or any of the other ingredients of Latanoprost/Timolol Zentiva (listed in section 6).
- have now or have had in past severe breathing problems such as asthma, severe chronic obstructive bronchitis (severe lung disease which may cause wheeziness, difficulty in breathing and/or long-standing cough).
- have serious heart problems or heart rhythm disorders.

## **Warnings and precautions**

Talk to your doctor or pharmacist before using Latanoprost/Timolol Zentiva if you have now or have had in the past

- heart problems such as coronary heart disease (symptoms can include chest pain or tightness, breathlessness or choking), heart failure, low blood pressure, disturbances of heart rate such as bradycardia (slow heart rate), Prinzmetal's angina (chest pain occurs at rest). If using Latanoprost/Timolol Zentiva you should watch for signs of deterioration of these illnesses.
- breathing problems, asthma or chronic obstructive pulmonary disease.
- poor blood circulation disease such as Raynaud's disease or Raynaud's syndrome (discolouration of fingertips in response to cold accompanied by pain).
- diabetes or low blood sugar levels (hypoglycaemia) as timolol may mask signs and symptoms of low blood sugar.
- overactivity of the thyroid gland as timolol may mask signs and symptoms.
- you are about to have any kind of eye surgery (including cataract surgery) or have had any kind of eye surgery in the past.
- eye problems (such as eye pain, eye irritation, eye inflammation or blurred vision, dry eyes or cornea problems, problems with choroidea).
- take beta-blocking drugs (used for therapy of high blood pressure, rapid heart rate etc.).
- severe allergic reactions that would usually require hospital treatment.
- a viral infection of the eye caused by the herpes simplex virus (HSV).
- wear contact lenses. You can still use Latanoprost/Timolol Zentiva but follow the instructions for contact lens wearers in section 3.

Tell your doctor before you have an operation that you use Latanoprost/Timolol Zentiva as timolol may change effects of some medicines used during anaesthesia.

Your doctor may want you to have extra checks on your heart and circulation if you use Latanoprost/Timolol Zentiva.

## **Other medicines and Latanoprost/Timolol Zentiva**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including using eye drops and medicines obtained without a prescription.

Latanoprost/Timolol Zentiva can affect or be affected by other medicines you are using, including other eye drops for the treatment of glaucoma. Tell your doctor if you are using or intend to use medicines to lower blood pressure, heart medicine or medicines to treat diabetes.

In particular, speak to your doctor or pharmacist if you know that you are taking any of the following types of medicine:

- Prostaglandins, prostaglandin analogues or prostaglandin derivatives.
- Beta-blockers.
- Epinephrine.
- Drugs used to treat high blood pressure such as oral calcium channel blockers, guanethidine, antiarrhythmics (including amiodarone, quinidine - used to treat heart conditions and some types of malaria), digitalis glycosides or parasympathomimetics.
- Antidepressants fluoxetine and paroxetine.

### **Using Latanoprost/Timolol Zentiva with food, drink and alcohol**

Normal meals, food or drink have no effect on when or how you should use Latanoprost/Timolol Zentiva.

### **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 or pharmacist for advice before using this medicine.

#### Pregnancy

Do not use Latanoprost/Timolol Zentiva if you are pregnant unless your doctor considers it necessary.

#### Breast-feeding

Do not use Latanoprost/Timolol Zentiva you are breast-feeding. Latanoprost/Timolol Zentiva may get into your milk.

#### Fertility

Latanoprost and timolol have been found to have no effect on male or female fertility in animal studies.

### **Driving and using machines**

When you use Latanoprost/Timolol Zentiva your vision may become blurred for a short time. If this happens to you, do not drive or use any tools or machines until your vision becomes clear again.

### **Latanoprost/Timolol Zentiva contains benzalkonium chloride and phosphate buffers**

This medicine contains 0.412 mg benzalkonium chloride 50% in each ml. Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards (see section 3.). Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

This medicine contains 9.28 mg/ml phosphates. If you suffer from severe damage to the clear layer at the front of the eye (the cornea), phosphates may cause in very rare cases cloudy patches on the cornea due to calcium build-up during treatment.

## **3. How to use Latanoprost/Timolol Zentiva**

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

**The recommended dose** for adults (including the elderly) is one drop once a day in the affected eye(s).

Do not use Latanoprost/Timolol Zentiva more than once a day, because the effectiveness of the treatment can be reduced if you administer it more often.

Use Latanoprost/Timolol Zentiva as instructed by your doctor until your doctor tells you to stop. Your doctor may want you to have extra checks on your heart and circulation if you use Latanoprost/Timolol Zentiva.

### **Contact lens wearers**

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

### **Instructions for use**

Follow the steps below to help you use Latanoprost/Timolol Zentiva properly:

1. Wash your hands and sit or stand comfortably.
2. Unscrew the outer protective cap.
3. Use your finger to gently pull down the lower eyelid of your affected eye until there is a 'pocket' between the eyelid and your eye. The drop will go in here.
4. Place the tip of the bottle close to your eye. Do not touch your eye or eyelid, surrounding areas or other surfaces with the dropper. It could infect the drops.



5. Squeeze the bottle gently so that only one drop goes into your eye and then release the lower eyelid.
6. After using Latanoprost/Timolol Zentiva press a finger against the corner of the affected eye by the nose. Hold for 2 minutes whilst keeping the eye closed. This helps to stop Latanoprost/Timolol Zentiva getting into the rest of the body.



7. If you use drops in both eyes, repeat the steps for your other eye.
8. If a drop misses your eye, try again.
9. Put the cap back on the bottle.

### **If you use Latanoprost/Timolol Zentiva with other eye drops**

Wait at least 5 minutes between using Latanoprost/Timolol Zentiva and using the other eye drops.

### **If you use more Latanoprost/Timolol Zentiva than you should**

If you put too many drops in your eye you may experience some minor irritation in your eye and your eyes may water and turn red. This should pass but if you are worried contact your doctor for advice.

### **If you swallow Latanoprost/Timolol Zentiva**

If you swallow Latanoprost/Timolol Zentiva accidentally you should contact your doctor for advice. If you swallow a lot of Latanoprost/Timolol Zentiva you may feel sick, have stomach pains, feel tired, flushed and dizzy and start to sweat.

### **If you forget to use Latanoprost/Timolol Zentiva**

Carry on with the usual dosage at the usual time. Do not use a double dose to make up for a forgotten dose.

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. You can usually carry on using the drops, unless the effects are serious. If you are worried, talk to a doctor or pharmacist. Do not stop using Latanoprost/Timolol Zentiva without speaking to your doctor.

Listed below are the known side effects of Latanoprost/Timolol Zentiva.

The most important side-effect is the possibility of a gradual, permanent change in your eye colour.

It is also possible that Latanoprost/Timolol Zentiva might cause serious changes in the way your heart works. **Tell your doctor immediately** that you have been using Latanoprost/Timolol Zentiva if you notice changes in your heart rate or heart function.

The following are known side effects reported to date in terms of their frequency:

**Very common** (*may affect more than 1 in 10 people*):

- A gradual change in your eye colour by increasing the amount of brown pigment in the coloured part of the eye known as the iris. If you have mixed-colour eyes (blue-brown, grey-brown, yellow-brown or green-brown) you are more likely to see this change than if you have eyes of one colour (blue, grey, green or brown eyes). Any changes in your eye colour may take years to develop. The colour change may be permanent and may be more noticeable if you use Latanoprost/Timolol Zentiva in only one eye. There appears to be no problems associated with the change in eye colour. The eye colour change does not continue after Latanoprost/Timolol Zentiva treatment is stopped.

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

- Eye irritation (a feeling of burning, grittiness, itching, stinging or the sensation of a foreign body in the eye) and eye pain.

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

- Headache.
- Redness of the eye, eye infection (conjunctivitis), blurred vision, watery eyes, inflammation of the eyelids, irritation or disruption of the surface of the eye.
- Nausea, vomiting
- Skin rashes or itching (pruritus).

#### Other side effects

Although not seen with Latanoprost/Timolol Zentiva, the following additional side effects have been seen with the medicines in Latanoprost/Timolol Zentiva (latanoprost and timolol) and therefore might occur when you use Latanoprost/Timolol Zentiva:

Like other medicines used in the eyes, Latanoprost/Timolol Zentiva is absorbed into the blood. The timolol portion of this combination may cause similar side effects as seen with 'intravenous' and/or 'oral' beta-blocking agents. The incidence of side effects after using eye drops is lower than when medicines are, for example, taken by mouth or injected.

- Developing a viral infection of the eye caused by the herpes simplex virus (HSV).
- Generalized allergic reactions including swelling beneath the skin that can occur in areas such as the face and limbs and can obstruct the airway which may cause difficulty

- swallowing or breathing, hives or itchy rash, localized and generalized rash, itchiness, severe sudden life-threatening allergic reaction.
- Low blood glucose levels.
- Dizziness.
- Difficulty sleeping (insomnia), depression, nightmares, memory loss, hallucination.
- Fainting, stroke, reduced blood supply to the brain, increases in signs and symptoms of myasthenia gravis (muscle disorder), unusual sensations like pins and needles, and headache.
- Swelling at the back of the eye (macular oedema), fluid filled cyst within the coloured part of the eye (iris cyst), light sensitivity (photophobia), sunken eye appearance (deepening of the eye sulcus).
- Signs and symptoms of eye irritation (e.g. burning, stinging, itching, tearing, redness), inflammation of the eyelid, inflammation in the cornea, blurred vision and detachment of the layer below the retina that contains blood vessels following filtration surgery which may cause visual disturbances, decreased corneal sensitivity, dry eyes, corneal erosion (damage to the front layer of the eyeball), drooping of the upper eyelid (making the eye stay half closed), double vision.
- Darkening of the skin around the eyes, changes to the eyelashes and fine hairs around the eye (increased number, length, thickness and darkening), changes to the direction of eyelash growth, swelling around the eye, swelling of the coloured part of the eye (iritis/uveitis), scarring of the surface of the eye.
- Whistling/ringing in the ears (tinnitus).
- Angina, worsening of angina in patients who already have heart disease. Slow heart rate, chest pain, palpitations (awareness of heart rhythm), oedema (fluid build-up), changes in the rhythm or speed of the heartbeat, congestive heart failure (heart disease with shortness of breath and swelling of the feet and legs due to fluid build-up), a type of heart rhythm disorder, heart attack, heart failure.
- Low blood pressure, poor blood circulation which makes the fingers and toes numb and pale, cold hands and feet.
- Shortness of breath, constriction of the airways in the lungs (predominantly in patients with pre-existing disease), difficulty breathing, cough, asthma, worsening of asthma.
- Taste disturbances, nausea, indigestion, diarrhoea, dry mouth, abdominal pain, vomiting.
- Hair loss, skin rash with white silvery coloured appearance (psoriasisiform rash) or worsening of psoriasis, skin rash.
- Joint pain, muscle pain not caused by exercise, muscle weakness, tiredness.
- Sexual dysfunction, decreased libido.

In very rare cases, some patients with severe damage to the clear layer at the front of the eye (the cornea) have developed cloudy patches on the cornea due to calcium build-up during treatment.

### **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 to HPRA 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 Latanoprost/Timolol Zentiva**

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 bottle and box after EXP.

The expiry date refers to the last day of that month.

Before first opening store in a refrigerator (2 °C – 8 °C).

Once the bottle has been opened, do not store above 25 °C. After opening, do not use this bottle for more than 4 weeks. Write down the date you open it.

Keep the bottle in the outer carton in order to protect the medicine from light.

Do not use this medicine if you notice the bottle is damaged or eye drops do not look right in some other way.

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 Latanoprost/Timolol Zentiva contains**

- The active substances are latanoprost and timolol maleate. 1 ml of Latanoprost/Timolol Zentiva contains latanoprost 50 micrograms and timolol maleate 6.83 mg equivalent to 5 mg timolol.
- The other ingredients are: sodium chloride, sodium dihydrogen phosphate monohydrate, disodium phosphate anhydrous, benzalkonium chloride, hydrochloric acid, sodium hydroxide, water for injections.

### **What Latanoprost/Timolol Zentiva looks like and contents of the pack**

The solution is a clear colourless, odourless liquid.

Each bottle contains 2.5 ml eye drop solution.

Pack sizes:

1×2.5 ml

3×2.5 ml

4×2.5 ml

6×2.5 ml

8×2.5 ml

12×2.5 ml

Not all pack sizes may be marketed.

### **Marketing authorisation holder**

Zentiva k.s,  
U kabelovny 130,  
102 37 Prague 10,  
Czech Republic

### **Manufacturer**

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