

## **Package Leaflet: Information for the user**

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

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

Latanoprost/Timolol Pfizer 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 Pfizer 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 Pfizer when other medicines have not worked adequately.

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

Latanoprost/Timolol Pfizer 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 Pfizer:**

- if you are allergic (hypersensitive) to either of the medicines in Latanoprost/Timolol Pfizer (latanoprost or timolol), beta-blockers, or any of the other ingredients of Latanoprost/Timolol Pfizer (listed in section 6)
- if you have now or have had in past respiratory problems such as asthma, severe chronic obstructive bronchitis (severe lung disease which may cause wheeziness, difficulty in breathing and/or long-standing cough)
- if you have serious heart problems or heart rhythm disorders
- if you are pregnant (or trying to become pregnant)
- if you are breast-feeding

### **Warnings and precautions**

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

- coronary heart disease – symptoms can include chest pain or tightness, breathlessness or choking, heart failure, low blood pressure (hypotension)
- disturbances of heart rate such as slow heart beat (bradycardia)
- breathing problems, asthma or chronic obstructive pulmonary disease (lung disease which may cause wheeziness, difficulty in breathing and/or long standing cough)
- poor blood circulation disease (peripheral arterial disease such as Raynaud’s disease or Raynaud’s syndrome)
- diabetes 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

- you suffer from eye problems (such as eye pain, eye irritation, eye inflammation or blurred vision)
- you know that you suffer from dry eyes
- you wear contact lenses. You can still use Latanoprost/Timolol Pfizer but follow the instructions for contact lens wearers in section 3
- you know that you suffer from angina (particularly a type known as Prinzmetal angina)
- you know that you suffer from severe allergic reactions that would usually require hospital treatment
- you have suffered or are currently suffering from an viral infection of the eye caused by the herpes simplex virus (HSV)

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

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

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 Pfizer 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, digitalis glycosides or parasympathomimetics
- Quinidine (used to treat heart conditions and some types of malaria)
- Antidepressants known as fluoxetine and paroxetine

### **Latanoprost/Timolol Pfizer with food and drink**

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

### **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.

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 Pfizer 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 Pfizer contains benzalkonium chloride**

Latanoprost/Timolol Pfizer contains a preservative called benzalkonium chloride. This preservative may cause eye irritation or disruption to the surface of the eye. It can be absorbed by contact lenses and is known to discolour soft contact lenses. Therefore, avoid contact with soft contact lenses. See the instructions for contact lens wearers in section 3.

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

Always use this medicine exactly as your doctor or pharmacist 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 Pfizer more than once a day, because the effectiveness of the treatment can be reduced if you administer it more often.

Use Latanoprost/Timolol Pfizer 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 Pfizer.

## Contact lens wearers

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

### Instructions for use

1. Wash your hands and sit or stand comfortably.
2. Twist off the outer cap (which can be thrown away).

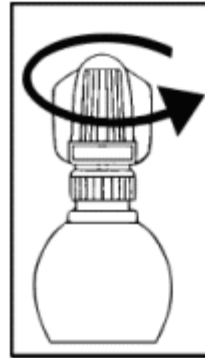


Figure 1

3. Unscrew the protective inner cap. The protective cap should be retained.



Figure 2

4. Use your finger to gently pull down the lower eyelid of your affected eye.
5. Place the tip of the bottle close to, but not touching your eye.
6. Squeeze the bottle gently so that only one drop goes into your eye, then release the lower eyelid.

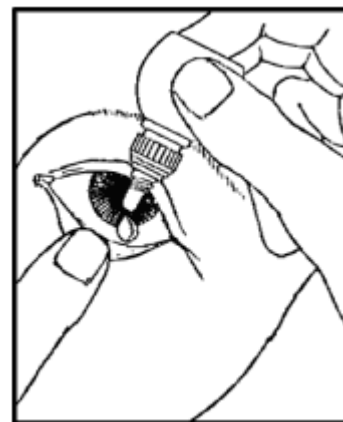


Figure 3

7. After using Latanoprost/Timolol Pfizer, press a finger into the corner of your eye, by the nose (figure 4) for 2 minutes. This helps to stop latanoprost + timolol getting into the rest of the body.



**Figure 4**

8. Repeat in your other eye if your doctor has told you to do this.
9. Put the protective inner cap back on the bottle.

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

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

### **If you use more Latanoprost/Timolol Pfizer 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 Pfizer**

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

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

Carry on with the usual dosage at the usual time. Do not take a double dose to make up to the dose you have forgotten. If you are unsure about anything talk to 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 taking the drops, unless the effects are serious. If you're worried, talk to a doctor or pharmacist. Do not stop using Latanoprost/Timolol Pfizer without speaking to your doctor.

Listed below are the known side effects of using Latanoprost/Timolol Pfizer. The most important side-effect is the possibility of a gradual, permanent change in your eye colour. It is also possible that Latanoprost/Timolol Pfizer might cause serious changes in the way your

heart works. If you notice changes in your heart rate or heart function you should speak to a doctor and tell them you have been using Latanoprost/Timolol Pfizer.

The following are known side effects of using Latanoprost/Timolol Pfizer:

**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 Pfizer 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 Pfizer 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
- Skin rashes or itching (pruritus)

**Other side effects**

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

Infections and Infestations:

- Developing a viral infection of the eye caused by the herpes simplex virus (HSV).

Immune System Disorders:

- Symptoms of allergic reaction (swelling and redness of the skin and rash).

Psychiatric Disorders:

- Depression, memory loss, decreased sex drive, inability to sleep, nightmares.

Nervous System Disorders:

- Dizziness, tingling or numbness in the skin, changes in blood flow to the brain, worsening of symptoms of myasthenia gravis (if you already suffer from this condition), sudden fainting or feeling you may faint (syncope).

#### Eye Disorders:

- 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), swelling at the back of the eye (macular oedema), inflammation/irritation of the surface of the eye (keratitis), dry eyes, visual changes/disturbances, double vision, drooping of the upper eyelid, injury to the lining of the back of the eye (a condition known as retinal detachment, but only seen when used following some kinds of eye surgery), fluid filled cyst with the coloured part of the eye (iris cyst), light sensitivity (photophobia), sunken eye appearance (deepening of the eye sulcus).

#### Ear Disorders:

- Whistling/ringing in the ears (tinnitus).

#### Heart (Cardiac) Disorders:

- Worsening of angina, awareness of heart rhythm (palpitations), changes in heart rhythm, slowing of the heart, heart failure (cardiac arrest, heart block or congestive heart failure).

#### Blood flow (Vascular) Disorders:

- Low blood pressure, discolouration/coldness of the fingers and toes (Raynaud's phenomenon) and coldness of the hands and feet.

#### Breathing (Respiratory) Disorders:

- Asthma, worsening of asthma, shortness of breath, sudden difficulty to breathe (bronchospasm), cough.

#### Digestive System (Gastrointestinal) Disorders:

- Feeling sick (nausea), diarrhoea, dyspepsia, dry mouth.

#### Skin Disorders:

- Darkening of the skin around the eyes, hair loss/baldness (alopecia), itchy rash or worsening of itchy skin conditions.

#### Muscle and Skeletal Disorders:

- Joint pain, muscle pain

#### General Disorders:

- Chest pain, fatigue, swelling (oedema)

Like other medicines applied into the eyes (topically applied ophthalmic drugs), Latanoprost/Timolol Pfizer is absorbed into the blood. This may cause similar side effects as seen with systemic beta-blocking agents. Side effects after topical application into the eyes

are lower than when medicines are, for example, taken by mouth or injected. Listed side effects include reactions seen within the class of beta-blockers when used for treating eye conditions:

- Allergic reactions including sudden swelling of the face, lips, mouth, tongue or throat which may cause difficulty swallowing or breathing (angioedema), hives (urticaria), localized and generalized rash, itchiness (pruritus), sudden life-threatening allergic reaction (anaphylactic reaction).
- Low sugar levels in the blood (hypoglycaemia).
- Difficulty sleeping (insomnia), depression, nightmares, memory loss.
- Fainting (syncope), stroke (cerebrovascular accident), decreased blood flow to parts of the brain (cerebral ischemia), increases in signs and symptoms of myasthenia gravis (muscle disorder), dizziness, tingling or numbness of hands and feet, pins and needles (paraesthesia), headache.
- Signs and symptoms of eye irritation (e.g. burning, stinging, itching, tearing, redness), swollen eyelid (blepharitis), irritation or feeling of having something in the eye (keratitis), blurred vision and low eye pressure and visual disturbances after an eye operation (choroidal detachment following filtration surgery), decreased corneal sensitivity, dry eyes, damage to the front layer of the eyeball (corneal erosion), drooping of the upper or lower eyelid (ptosis), double vision (diplopia).
- Slow heart beat (bradycardia), chest pain, palpitations, fluid build up (oedema), changes in the rhythm or speed of the heart beat (arrhythmia), heart disease with shortness of breath and swelling of the feet and legs due to fluid build up (congestive heart failure), heart condition (atrioventricular block), heart attack (cardiac arrest), heart (cardiac) failure.
- Low blood pressure (hypotension), poor blood circulation which makes the toes and fingers numb and change colour (Raynaud's phenomenon), cold hands and feet.
- Bronchospasm (wheezing or difficulty breathing – usually in patients with pre-existing bronchospastic disease), shortness of breath (dyspnoea), cough.
- Taste disturbances (dysgeusia), nausea, indigestion (dyspepsia), diarrhoea, dry mouth, abdominal pain, vomiting.
- Hair loss (alopecia), skin rash with white silvery coloured appearance (psoriasiform rash) or worsening of psoriasis, skin rash.
- Muscle weakness or pain not caused by exercise (myalgia). sexual dysfunction, decreased libido.
- Unusual muscle weakness or pain not caused by exercise (asthenia) or tiredness (fatigue).

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax:

+353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Latanoprost/Timolol Pfizer**

Keep this medicine out of the sight and reach of children.

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

Store the unopened bottle of Latanoprost/Timolol Pfizer in a refrigerator (between 2°C to 8°C). After the first opening of the bottle it is not necessary to store it in a refrigerator but do not store it above 25°C. After the first opening do not use this bottle for more than 4 weeks. When you are not using Latanoprost/Timolol Pfizer, keep the bottle in the outer carton, in order to protect from light.

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 Pfizer contains**

The active substances are latanoprost 50 micrograms/mL and timolol (as timolol maleate) 5 mg/mL.

The other ingredients are:

Sodium chloride  
Benzalkonium chloride  
Sodium dihydrogen phosphate monohydrate  
Disodium phosphate anhydrous  
Hydrochloric acid solution (for adjustment to pH 6.0)  
Sodium hydroxide solution (for adjustment to pH 6.0)  
Water for injections

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

This pack contains one bottle containing 2.5 mL of Latanoprost/Timolol Pfizer Eye Drops, Solution.

Latanoprost/Timolol Pfizer is a clear, colourless liquid.

Latanoprost/Timolol Pfizer is available in pack sizes of 1, 3 and 6 bottles. Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

Marketing Authorisation Holder:

Pfizer Healthcare Ireland  
9 Riverwalk  
National Digital Park  
Citywest Business Campus  
Dublin 24, Ireland

Manufacturer:

Pfizer Manufacturing Belgium NV, Rijksweg 12, 2870 Puurs, Belgium.

**This medicinal product is authorised in the Member States of the EEA under the following names:**

Latanoprost/Timolol Pfizer – Austria, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Netherlands, Norway, Portugal, Sweden  
Latanoprost/Timolol Pharmacia – Spain  
Latanoprost/Timolol - UK

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