

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

### **Travoprost/Timolol 40 micrograms/ml+ 5 mg/ml eye drops, solution**

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

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

Travoprost/Timolol eye drops solution is a combination of two active substances (travoprost and timolol). Travoprost is a prostaglandin analogue which works by increasing the outflow of liquid (aqueous fluid) from the eye, which lowers its pressure. Timolol is a beta blocker which works by reducing the production of fluid within the eye. The two substances work together to reduce pressure within the eye.

Travoprost/Timolol eye drops are used to treat high pressure in the eye in adults, including the elderly. This pressure can lead to an illness called glaucoma.

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

##### **Do not use Travoprost/Timolol**

- if you are allergic to travoprost, timolol, or any of the other ingredients of this medicine (listed in section 6)
- if you are allergic to any prostaglandins or beta blockers
- if you have now or have had in the 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) or other types of breathing problems
- if you have severe hay fever
- if you have a slow heartbeat, heart failure or disorder of heart rhythm (irregular heartbeat)
- if the surface of your eye is cloudy.

Ask your doctor for advice if any of these apply to you.

#### **Warnings and precautions**

Talk to your doctor or pharmacist before using Travoprost/Timolol 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
- disturbances of heart rate such as slow heart-beat
- breathing problems, asthma or chronic obstructive pulmonary disease
- poor blood circulation 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 of thyroid disease
- myasthenia gravis (chronic neuromuscular weakness)
- cataract surgery
- an eye inflammation.

If you need to have any type of surgery, tell your doctor that you are using Travoprost/Timolol as timolol may change the effects of some medicines used during anaesthesia.

If you get any severe allergic reaction (skin rash, redness and itching of the eye) while using Travoprost/Timolol, whatever the cause, adrenaline treatment may not be as effective. It is therefore important to tell the doctor that you are using Travoprost/Timolol when you are to receive any other treatment.

Travoprost/Timolol may change the colour of your iris (the coloured part of your eye). This change may be permanent.

Travoprost/Timolol may increase the length, thickness, colour and/or number of your eyelashes and may cause unusual hair growth on your eyelids.

Travoprost may be absorbed through the skin and therefore should not be used by women who are pregnant or are attempting to become pregnant. If any of the medicine comes into contact with the skin then it should be washed off straight away.

### **Children**

Travoprost/Timolol is not to be used by children and adolescents under 18 years of age.

### **Other medicines and Travoprost/Timolol**

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

Travoprost/Timolol 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 including quinidine (used to treat heart conditions and some types of malaria)
- medicines to treat diabetes or antidepressants known as fluoxetine and paroxetine

### **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.

Do not use Travoprost/Timolol if you are pregnant unless your doctor considers it necessary. If you could get pregnant you must use adequate contraception whilst you use the medicine.

Do not use Travoprost/Timolol if you are breast-feeding. This medicine may get into your milk.

### **Driving and using machines**

You may find that your vision is blurred for a time just after you use Travoprost/Timolol. Travoprost /Timolol may also cause hallucinations, dizziness, nervousness or fatigue in some patients.

Do not drive or use machines until this has worn off.

### **Travoprost/Timolol contains benzalkonium chloride and macrogolglycerol hydroxystearate 40**

This medicine contains 150 micrograms of benzalkonium chloride in each ml of solution.

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.

Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the 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.

Macrogolglycerol hydroxystearate 40 may cause skin reactions.

### **3. How to use Travoprost/Timolol**

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

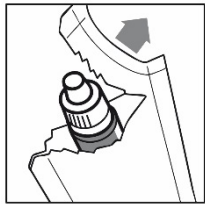
#### **The recommended dose is:**


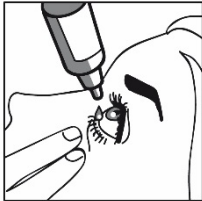

One drop in the affected eye or eyes, once a day in the morning or in the evening. Use at the same time each day.

Only use Travoprost/Timolol in both eyes if your doctor told you to do so. Use it for as long as your doctor told you to.

Only use Travoprost/Timolol for dropping in your eyes.

#### **Instructions for use**

 <p><b>1</b></p>	<ul style="list-style-type: none"><li>• Immediately before using a bottle for the first time, tear-off the sachet (<b>picture 1</b>). Take out the bottle and write the date of opening on the label in the space provided.</li><li>• Get the medicine bottle and a mirror.</li><li>• Wash your hands.</li><li>• Twist off the cap.</li></ul>
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 <p>2</p>	<ul style="list-style-type: none"> <li>• Hold the bottle, pointing down, between your thumb and fingers.</li> <li>• Tilt your head back. Pull down your eyelid with a clean finger, until there is a 'pocket' between the eyelid and your eye. The drop will go in here (<b>picture 2</b>).</li> <li>• Bring the bottle tip close to the eye. Use the mirror if it helps.</li> </ul>
 <p>3</p>	<ul style="list-style-type: none"> <li>• <b>Do not touch your eye or eyelid, surrounding areas or other surfaces with the dropper.</b> It could infect the drops.</li> <li>• Gently squeeze the bottle to release one drop of medicine at a time (<b>picture 3</b>).</li> </ul>
 <p>4</p>	<ul style="list-style-type: none"> <li>• After using the medicine, press a finger into the corner of your eye, by the nose for 2 minutes (<b>picture 4</b>). This helps to stop the medicine getting into the rest of the body.</li> <li>• If you use drops in both eyes, repeat these same steps for your other eye.</li> <li>• Close the bottle cap firmly immediately after use.</li> <li>• Only use one bottle of medicine at a time. Do not open the sachet until you need to use the bottle.</li> <li>• <b>You must throw away the bottle 4 weeks after you first opened it,</b> to prevent infections, and use a new bottle.</li> </ul>

**If a drop misses your eye, try again.**

**If you use more Travoprost/Timolol than you should**

If you use more Travoprost/Timolol than you should, rinse it all out with warm water. Do not put in any more drops until it is time for your next regular dose.

**If you forget to use Travoprost/Timolol**

If you forget to use Travoprost/Timolol, continue with the next dose as planned. Do not use a double dose to make up for a forgotten dose. The dose should not exceed one daily drop in the affected eye(s).

**If you stop using Travoprost/Timolol**

If you stop using Travoprost/Timolol without speaking to your doctor the pressure in your eye will not be controlled which could lead to loss of sight.

If you are using other eye drops in addition to Travoprost/Timolol, leave at least 5 minutes between putting in Travoprost/Timolol and the other drops.

If you wear soft contact lenses do not use the drops with your lenses in. After using the drops wait 15 minutes before putting your lenses back in.

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 taking the drops, unless the effects are serious. If you are worried, talk to a doctor or pharmacist. Do not stop using Travoprost/Timolol without speaking to your doctor.

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

*Effects in the eye:*

- eye redness.

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

*Effects in the eye:*

- eye surface inflammation with surface damage
- eye pain
- blurred vision
- abnormal vision
- dry eye
- itchy eye
- eye discomfort
- signs and symptoms of eye irritation (e.g. burning, stinging).

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

*Effects in the eye:*

- inflammation of the eye surface
- inflammation of the eyelid
- swollen conjunctiva
- increased growth of eyelashes
- iris inflammation
- eye inflammation
- sensitivity to light
- reduced vision
- tired eyes
- eye allergy
- eye swelling
- increased tear production
- eyelid redness
- eyelid colour change
- skin darkening (around the eye).

*General side effects:*

- allergic reaction
- dizziness
- headache
- increased or decreased blood pressure
- shortness of breath
- excessive hair growth
- drip at back of throat
- skin inflammation and itching
- decreased heart rate.

**Rare side effects (may affect up to 1 in 1,000 people):**

*Effects in the eye:*

- thinning of the eye surface

- inflammation of the eyelid glands
- broken blood vessel in the eye
- eyelid crusting
- abnormally positioned eyelashes
- abnormal growth of lashes.

*General side effects:*

- nervousness
- irregular heart rate
- loss of hair
- voice disorders
- difficulty breathing
- cough
- throat irritation
- hives
- abnormal liver blood tests
- skin discolouration
- thirst
- tiredness
- discomfort inside of nose
- coloured urine
- pain in hands and feet.

**Not known (frequency cannot be estimated from the available data):**

*Effects in the eye:*

- droopy eyelid (making the eye stay half closed)
- sunken eyes (eyes appear more inset)
- changes in the colour of the iris (coloured part of the eye).

*General side effects:*

- rash
- heart failure
- chest pain
- stroke
- fainting
- depression
- asthma
- increased heart rate
- numbness or tingling sensation
- palpitations
- swelling in the lower limbs
- bad taste.

Additionally:

Travoprost/Timolol is a combination of two active substances, travoprost and timolol. Like other medicines applied into eyes, travoprost and timolol (a beta blocker) are absorbed into the blood. This may cause similar side effects as seen when beta-blocking medicines are taken by mouth or injected. The incidence of side effects when applied into the eyes is lower than when medicines are taken by mouth or injected. The side effects listed below include reactions seen within the class of beta blockers used for treating eye conditions or reactions seen with travoprost alone:

*Effects in the eye:*

- inflammation of the eyelid
- inflammation in the cornea
- detachment of the layer below the retina that contains blood vessels following filtration surgery which may cause visual disturbances
- decreased corneal sensitivity
- corneal erosion (damage to the front layer of the eyeball)
- double vision
- eye discharge
- swelling around the eye
- eyelid itching
- outward turning of eyelid with redness
- irritation and excessive tears
- blurred vision (sign of clouding of the eye lens)
- swelling of a section of the eye (uvea)
- eczema of the eyelids
- halo vision
- decreased eye sensation
- pigmentation inside the eye
- dilated pupils
- change in eyelash colour
- change in the texture of the eyelashes
- abnormal field of vision.

*General side effects:*

*Ear and labyrinth disorders:*

- \* dizziness with spinning sensation
- \* ringing in the ears.

*Heart and circulation:*

- \* slow heart rate
- \* 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
- \* low blood pressure
- \* Raynaud's phenomenon
- \* cold hands and feet,
- \* reduced blood supply to the brain.

*Respiratory:*

- \* worsening of asthma
- \* runny or stuffy nose
- \* sneezing (due to allergy),
- \* difficulty breathing
- \* nose bleed
- \* nasal dryness.

*Nervous system and general disorders:*

- \* difficulty sleeping (insomnia)
- \* nightmares
- \* memory loss
- \* loss of strength and energy
- \* anxiety (excessive emotional distress)
- \* hallucinations.

*Gastrointestinal:*

- \* nausea
- \* indigestion
- \* diarrhoea
- \* dry mouth
- \* abdominal pain
- \* vomiting
- \* constipation.

*Allergy:*

- \* increased allergic symptoms
- \* generalised 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
- \* localised and generalised rash
- \* itchiness
- \* severe sudden life-threatening allergic reaction.

*Skin:*

- \* skin rash with white silvery coloured appearance (psoriasiform rash) or worsening of psoriasis
- \* peeling skin
- \* abnormal hair texture
- \* inflammation of the skin with itchy rash and redness
- \* hair colour change
- \* loss of eyelashes
- \* itching
- \* abnormal hair growth
- \* skin redness.

*Muscular:*

- \* increases in signs and symptoms of myasthenia gravis (muscle disorder)
- \* unusual sensations like pins and needles
- \* muscle weakness/tiredness
- \* muscle pain not caused by exercise
- \* joint pain.

*Renal and urinary disorders:* difficulty and pain when passing urine, involuntary leakage of urine.

*Reproduction:* sexual dysfunction, decreased libido.

*Metabolism:* low blood sugar levels, increase in prostate cancer marker.



### **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 the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for 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 Travoprost/Timolol**

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

Before opening, this medicine does not require any special temperature storage conditions. Keep the bottle in the sachet in order to protect from light.

After first opening, this medicine does not require any special storage conditions.

**You must throw away the bottle 4 weeks after you first opened it**, to prevent infections, and use a new bottle. Write down the date you opened the bottle in the space on the bottle label and box.

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 Travoprost/Timolol contains**

- The active substances are travoprost and timolol. Each ml of solution contains 40 micrograms of travoprost and 5 mg of timolol (as timolol maleate).
- The other ingredients are benzalkonium chloride, macrogolglycerol hydroxystearate 40, trometamol, edetate disodium, boric acid (E284), mannitol (E421), sodium hydroxide (for pH adjustment) and water for injection or purified water.

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

Travoprost/Timolol eye drops, solution is presented as a clear, colourless, aqueous solution, practically free from particles supplied in a 5 ml plastic bottle with colorless nozzle and white opaque cap with tamper proof seal.

Each bottle is enclosed in a sachet. Each bottle contains 2.5 ml solution.

The product is available in the following pack sizes:  
Cartons containing 1 or 3 bottles.

Not all pack sizes may be marketed.

#### **Marketing Authorisation Holder**

Mylan, Potters Bar, Hertfordshire, EN6 1TL. United Kingdom.

#### **Manufacturer**

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