

Package leaflet: Information for the user

[Invented name] 40 micrograms/ mL+ 5 mg/mL eye drops, solution travoprost/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 [Invented name] is and what it is used for
2. What you need to know before you use [Invented name]
3. How to use [Invented name]
4. Possible side effects
5. How to store [Invented name]
6. Contents of the pack and other information

1. What [Invented name] is and what it is used for

[Invented name] 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 of 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.

[Invented name] 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. [Invented name] eye drops solution is a sterile solution that does not contain a preservative.

2. What you need to know before you use [Invented name]

Do not use [Invented name]:

- 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 heart beat, heart failure or disorders of heart rhythm (irregular heart beats)
- 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 [Invented name] 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)
- any severe allergic reaction (skin rash, redness and itching of the eye) while using [Invented name], whatever the cause, adrenaline treatment may not be as effective. So when receiving any other treatment please tell the doctor that you are using [Invented name]
- a cataract surgery
- an eye inflammation (current or previous)

Tell your doctor before you have an operation that you are using [Invented name] as timolol may change effects of some medicines used during anaesthesia.

[Invented name] may change the colour of your iris (the coloured part of your eye). This change may be permanent.

[Invented name] 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

[Invented name] is not to be used by children and adolescents under 18 years of age.

Other medicines and [Invented name]

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

[Invented name] 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 [Invented name] 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 [Invented name] if you are breast-feeding. This medicine may get into your milk.

Ask your doctor for advice before taking any medicine during breast feeding.

Driving and using machines

You may find that your vision is blurred for a time just after you use [Invented name]. Do not drive or use machines until this has worn off.

[Invented name] contains macrogolglycerol hydroxystearate 40 and propylene glycol which may cause skin reactions and irritation.

3. How to use [Invented name]







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 [Invented name] in both eyes if your doctor told you to do so. Use it for as long as your doctor told you to.

Only use [Invented name] for dropping in your eyes.

Instructions for use

1a 	<ul style="list-style-type: none">• Take the multi-dose container (picture 1a) out of the carton box and write the date of opening on the carton box and the bottle in the space provided.
1b 	<ul style="list-style-type: none">• Get the medicine bottle and a mirror.• Wash your hands.• Remove the cap (picture 1b).
2 	<ul style="list-style-type: none">• Hold the bottle upside down with the thumb on the shoulder of the bottle and the other fingers on the bottom of the bottle. Before the first use, pump the bottle repeatedly, approximately 10 times, until the first drop emerges (picture 2).
3 	<ul style="list-style-type: none">• 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 (picture 3).• Bring the bottle tip close to the eye. Use the mirror if it helps.
4 	<ul style="list-style-type: none">• Do not touch your eye or eyelid, surrounding areas or other surfaces with the dropper. It could infect the drops.• Gently press down on the bottom side of the bottle to release one drop of medicine at a time (picture 4).• If a drop misses your eye, try again.
5 	<ul style="list-style-type: none">• After using the medicine, press a finger into the corner of your eye, by the nose for 2 minutes (picture 5). This helps to stop the medicine getting into the rest of the body.

- If you use drops in both eyes, repeat these same steps for your other eye.
- Close the multi-dose container cap firmly immediately after use.
- Only use one bottle of medicine at a time. Do not open the cap until you need to use the multi-dose container.
- **You must throw away the bottle 28 days after you first opened it**, to prevent infections, and use a new bottle.

If you use more [Invented name] than you should

If you use more [Invented name] 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 [Invented name]

If you forget to use [Invented name], 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 [Invented name]

If you stop using [Invented name] 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, leave at least 5 minutes between putting in [Invented name] 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're worried, talk to a doctor or pharmacist. Do not stop using [Invented name] 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.

General side effects: drug allergy, 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, skin darkening, 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)

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:

[Invented name] is a combination of 2 active substances. 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 with intravenous and/or oral beta-blocking medicines. The incidence of side effects after topical ophthalmic administration is lower than when medicines are, for example, taken by mouth or injected. Listed side effects which include reactions seen within the class of beta-blockers when used for treating eye conditions are as follows:

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, changes in the colour of the iris.

General side effects:

- Heart and circulation: slow heart rate, palpitations, 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: constriction of the airways in the lungs (predominantly in patients with pre-existing disease), difficulty breathing, stuffy nose.
- Nervous system and general disorders: difficulty sleeping (insomnia), nightmares, memory loss, loss of strength and energy.
- Gastric: taste disturbances, nausea, indigestion, diarrhea, dry mouth, abdominal pain, vomiting.
- Allergy: 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, localized and generalized rash, itchiness, severe sudden life-threatening allergic reaction.
- Skin: skin rash with white silvery coloured appearance (psoriasisiform rash) or worsening of psoriasis, peeling skin.
- 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.
- Reproduction: sexual dysfunction, decreased libido.
- Metabolism: low blood sugar levels.

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 national reporting system <to be completed nationally>. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Invented name]

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

Do not use this medicine if you notice that the multi dose container has been broken or damaged before you first open it.

This medicinal product does not require any special temperature storage conditions.

You must throw away the bottle 28 days after you first opened it, to prevent infections, and use a new bottle. Write down the date you opened the bottle in the space 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 [Invented name] 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 mannitol (E421), boric acid, sodium hydroxide, macroglycerol hydroxystearate (nominal value: 40), propylene glycol (E1520), sodium chloride and water purified.

What [Invented name] looks like and contents of the pack

[Invented name] eye drops, solution is presented as a 2.5 ml clear, colourless, aqueous solution in a cardboard box containing a 5 ml white plastic multi-dose container.

The product is available in the following pack sizes:

Cartons containing 1 or 3 number of bottles.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

<[To be completed nationally]>

This leaflet was last revised in