

**Package leaflet:
Information for the user**

**Travoprost/Timolol 40 micrograms/ml
+ 5mg/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

- What Travoprost/Timolol is and what it is used for
- What you need to know before you use Travoprost/Timolol
- How to use Travoprost/Timolol
- Possible side effects
- How to store Travoprost/Timolol
- 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 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 a disorder of heart rhythm (irregular heartbeat).
- if the surface of your eye is cloudy.

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

Warnings and precautions

Talk to your doctor 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 heartbeat.
- 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.
- 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 and adolescents

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.

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 medicines including quinidine (used to treat heart conditions and some types of malaria),

- medicines to treat diabetes or the antidepressants fluoxetine or 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. 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 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 in 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.

This medicine contains macrogolglycerol hydroxystearate 40, which 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.

Only use Travoprost/Timolol as eye drops.

Instructions for use

- Immediately before using a bottle for the first time, open the sachet (**picture 1**). Take the bottle out and write the date of opening on the label in the space provided.



- Make sure you have a mirror available.
- Wash your hands.
- Twist off the bottle cap.

- Hold the bottle, pointing down, between your thumb and fingers.



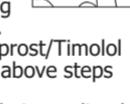
- Tilt your head back. Pull your lower eyelid down with a clean finger, until there is a 'pocket' between the eyelid and your eye. The drop will go in here (**picture 2**).

- Bring the bottle dropper close to the eye. Use the mirror if it helps.

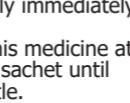
- Do not touch your eye or eyelid, the surrounding areas or other surfaces with the dropper.**



- It could infect the drops.
- Gently squeeze the bottle to release one drop of this medicine at a time (**picture 3**). If a drop misses your eye, try again.



- After using this medicine, press your finger into the corner of your eye, by your nose for 2 minutes (**picture 4**). This helps to stop this medicine getting into the rest of the body.



- If you have to use Travoprost/Timolol in both eyes, repeat the above steps for your other eye.

- Close the bottle cap firmly immediately after use.

- Only use one bottle of this medicine at a time. Do not open the sachet until you need to use the bottle.

- You must throw away the bottle 4 weeks after you first opened it**, to prevent the risk of infections, and start a new bottle.

Use Travoprost/Timolol for as long as your doctor has told you to.

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 take a double dose to make up for a forgotten dose. The dose should not exceed one drop daily 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 applying 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 using 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 to active substance, dizziness, headache, increased or decreased blood pressure, shortness of breath, excessive hair growth, drip at the back of the throat, skin inflammation and itching, decreased heart rate.

Rare (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), hallucination.

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 administered to the eyes, travoprost and timolol (a beta-blocker) are absorbed into the blood. This may cause side effects similar to those seen when beta-blocking medicines are administered by mouth or by injection. The incidence of side effects after administration to the eyes is lower than after administration by mouth or by injection.

The side effects listed below include reactions seen with 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, palpitations, oedema (fluid build-up), changes in heartbeat rhythm or speed, 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), 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).
- Gastrointestinal: taste disturbances, nausea, indigestion, diarrhoea, dry mouth, abdominal pain, vomiting and constipation.
- Allergy: increased allergic symptoms, 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, 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 (website: 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 the risk of infections. Each time you start a new bottle write down the date you open it in the spaces on the bottle label and carton.

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 5mg of timolol (as timolol maleate).
- The other ingredients are benzalkonium chloride, macroglycerol hydroxystearate 40, trometamol, edetate disodium, boric acid (E284), mannitol (E421), sodium hydroxide (for pH adjustment) and water for injections 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 5ml plastic bottle with colourless nozzle and white opaque cap with tamper proof seal.

Each bottle is enclosed in a sachet. Each bottle contains 2.5ml 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 and Manufacturer

Marketing Authorisation Holder:

Aspire Pharma Ltd
Unit 4, Rotherbrook Court,
Bedford Road

Petersfield
Hampshire

GU32 3QG

United Kingdom

Manufacturer:

Pharmathen S.A.,
6 Dervenakion
15351 Pallini Attiki

Greece

or

BALKANPHARMA-RAZGRAD AD
68 Aprilsko vastanie Blvd.,
Razgrad,
7200,

Bulgaria

or

JADRAN - GALENSKI LABORATORIJ d.d
Svilno 20
Rijeka 51000
Croatia

This leaflet was last revised in December 2019