

Package leaflet: Information for the user
DuoTrav® 40 micrograms/mL + 5 mg/mL eye drops, solution
(travoprost/timolol)

Your medicine is known as the above but will be referred to as DuoTrav throughout the remainder of this leaflet.

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

1. What DuoTrav is and what it is used for

DuoTrav eye drop 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.

DuoTrav 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 DuoTrav

Do not use DuoTrav

- if you are allergic to travoprost, prostaglandins, timolol, beta blockers or any of the other ingredients of this medicine (listed in section 6).
- 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.

Warning and precautions

Talk to your doctor before using DuoTrav 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 DuoTrav 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 DuoTrav, whatever the cause, adrenaline treatment may not be as effective. It is therefore important to tell the doctor that you are using DuoTrav when you are to receive any other treatment.

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

DuoTrav 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

DuoTrav is not to be used by children and adolescents under 18 years of age.

Other medicines and DuoTrav

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

DuoTrav 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 DuoTrav 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 DuoTrav if you are breast-feeding. DuoTrav may get into your milk.

Driving and using machines

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

Do not drive or use machines until any such symptoms has worn off.

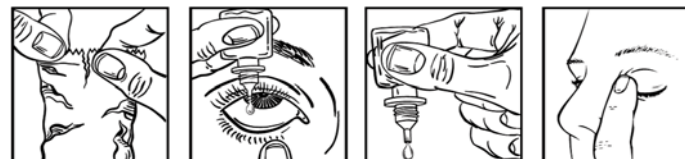
DuoTrav contains hydrogenated castor oil and propylene glycol which may cause skin reactions and irritation.

3. How to use DuoTrav

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 DuoTrav in both eyes if your doctor told you to do so. Only use DuoTrav as eye drops.



1. Immediately before using a bottle for the first time, tear open the overwrap (picture 1), remove the bottle and write the date of opening on the label in the space provided.
2. Make sure you have a mirror available.
3. Wash your hands.
4. Twist off the bottle cap.
5. Hold the bottle, pointing down, between your thumb and fingers.
6. 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).
7. Bring the bottle dropper close to the eye. Use the mirror if it helps.
8. Do not touch your eye or eyelid, the surrounding areas or other surfaces with the dropper. It could infect the drops.
9. Gently squeeze the bottle to release one drop of DuoTrav at a time (picture 3). If a drop misses your eye, try again.
10. After using DuoTrav, press your finger into the corner of your eye by your nose for 2 minutes (picture 4). This helps to stop DuoTrav getting into the rest of the body.
11. If you have to use DuoTrav in both eyes, repeat the above steps for your other eye.
12. Close the bottle cap firmly immediately after use.
13. Only use one bottle at a time. Do not open the overwrap until you need to use the bottle.

Use DuoTrav for as long as your doctor has told you to.

If you use more DuoTrav than you should

If you use more DuoTrav 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 DuoTrav

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

If you stop using DuoTrav

If you stop using DuoTrav 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 DuoTrav, leave at least 5 minutes between applying DuoTrav 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 DuoTrav without speaking to your doctor.

Very common side effects (may affect more than 1 in 10 people)

Effects in the eye

Eye redness.

Common side effects (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 side effects (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 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.