



**PACKAGE LEAFLET: INFORMATION FOR THE USER**

**DUOTRAV<sup>®</sup> 40 micrograms/mL + 5 mg/mL**  
**eye drops, solution**  
 travoprost/timolol

**Read all of this leaflet carefully before you start using this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your 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 any of the side effects gets serious, 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<sup>®</sup> is and what it is used for**

DuoTrav 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.

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 eye drops solution**

- if you are allergic to travoprost, prostaglandins, timolol, beta-blockers or any of the other ingredients.
- 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.

**Warning and Precautions**

Before you use this medicine, tell your doctor 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
- Tell your doctor before you have an operation that you are using DuoTrav as timolol may change effects of some medicines used during anaesthesia.
- If you have myasthenia gravis (chronic neuromuscular weakness).
- 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. So when receiving any other treatment please tell the doctor that you are using DuoTrav.
- If you have had cataract surgery talk to your doctor before you use DuoTrav.
- If you have current or previous history of an eye inflammation talk to your doctor before you use DuoTrav.

- 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**

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 medicine including quinidine (used to treat heart conditions and some types of malaria), medicines to treat diabetes or antidepressants known as fluoxetine and paroxetine.

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

**Pregnancy and breast-feeding and fertility**

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.

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

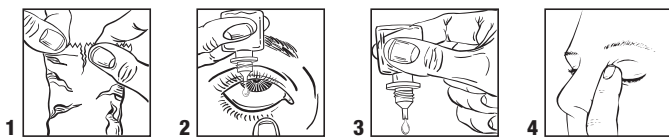
**Driving and using machines**

You may find that your vision is blurred for a time just after you use DuoTrav. Do not drive or use machines until this 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.



- Immediately before using a bottle for the first time, tear-off the overwrap pouch take it out (picture 1) and write the date of opening on the label in the space provided.
- Get the DuoTrav bottle and a mirror.
- Wash your hands.
- Twist off the cap.
- Hold the bottle, pointing down, between your thumb and fingers.
- 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 2).
- Bring the bottle tip close to the eye. Use the mirror if it helps.

**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. Use it for as long as your doctor told you to.

Only use DuoTrav for dropping in your eyes.

- Do not touch your eye or eyelid, surrounding areas or other surfaces with the dropper. It could infect the drops.
- Gently squeeze the bottle to release one drop of DuoTrav at a time (picture 3).
- After using DuoTrav, press a finger into the corner of your eye, by the nose for 2 minutes (picture 4). This helps to stop DuoTrav getting into the rest of the body.
- If you use drops in both eyes, repeat the steps for your other eye.
- Close the bottle cap firmly immediately after use.
- Only use one bottle at a time. Do not open the pouch until you need to use the bottle.

If a drop misses your eye, try again.

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

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, leave at least 5 minutes between putting in 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 other questions about your medicine, ask a 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 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.

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 1000 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 :

DuoTrav 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, diarrhoea, 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 (see details below).

By reporting side effects you can help provide more information on the safety of this medicine.

### United Kingdom

Yellow Card Scheme

Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

### Ireland

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)

### Malta

ADR Reporting

Website:

[www.medicinesauthority.gov.mt/adrportal](http://www.medicinesauthority.gov.mt/adrportal)

## 5 How to store DuoTrav

Keep out of the sight and reach of children.

Do not use DuoTrav eye drops solution after the expiry date which is stated on the bottle and outer carton after "EXP". The expiry date refers to the last day of the month.

Do not store above 30°C.

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 open it in the space on each bottle label and box.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

## 6 Contents of the pack and other information

### What DuoTrav 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 Polyquaternium-1, mannitol (E421), propylene glycol (E1520), polyoxyethylene hydrogenated castor oil 40, boric acid, sodium chloride, sodium hydroxide or hydrochloric acid (to adjust pH), purified water. Tiny amounts of sodium hydroxide or hydrochloric acid are added to keep acidity levels (pH levels) normal.

### What DuoTrav looks like and contents of the pack

DuoTrav is a liquid (a clear, colourless solution) supplied in a 2.5 mL plastic bottle with a screw cap.

Each bottle is placed in a pouch.

Packs of 1, 3 or 6 bottles.

Not all pack sizes may be marketed.

### Marketing Authorisation Holder

Alcon Laboratories (UK) Ltd., Frimley Business Park, Frimley, Camberley, Surrey GU16 7SR, United Kingdom

### Manufacturer

S.A. Alcon-Couvreur N.V., Rijksweg 14, B-2870 Puurs, Belgium

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

### Ireland

### Malta

### United Kingdom

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### This leaflet was last revised in January 2015.

Detailed information on this medicine is available on the European Medicines Agency website: <http://www.ema.europa.eu>

**Alcon**<sup>®</sup>  
a Novartis company