Package leaflet: Information for the user

DuoTrav® 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.

The name of your medicine is DuoTrav 40 micrograms/mL + 5mg/mL eye drops, solution but will be referred to as DuoTrav throughout this leaflet.

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 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 is 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.

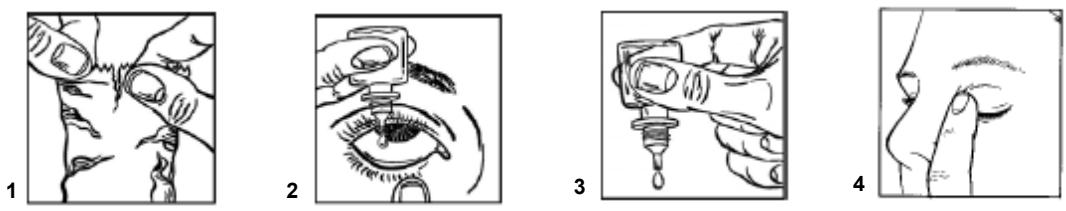
DuoTrav contains hydrogenated castor oil and propylene glycol which may cause skin reactions and irritation.

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.



- 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.
- 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 DuoTrav at a time (picture 3). If a drop misses your eye, try again.
- 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.
- If you have to use DuoTrav in both eyes, repeat the above steps for your other eye.
- Close the bottle cap firmly immediately after use.
- 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.

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:

DuoTrav 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 that 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, dilatated 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, hallucinations, 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, 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 Yellow Card Scheme at: 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 DuoTrav

Keep out of the sight and reach of children.

Do not store above 30°C.

Do not use the drops after the expiry date which is stated on the carton and bottle labels after 'Exp'. The expiry date refers to the last day of that month.

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.

Remember if your doctor tells you to stop taking this medicine, return any unused medicine to your pharmacist for safe disposal. Only keep this medicine if your doctor tells you to.

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 to protect the environment.

6. Contents of the pack and other information

What DuoTrav contains

The active ingredients in the DuoTrav are travoprost and timolol.
Each ml of solution contains 40 micrograms travoprost and 5mg 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) and 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 2.5mL plastic bottle with a screw cap. Each bottle is packed in an overwrap.

It is available in pack size of 1 or 3 bottles.

Manufactured by: Novartis Manufacturing NV, Rijksweg 14, 2870 Puurs-Sint-Amands, Belgium.
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OR
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Procured from within the EU and repackaged by the Product Licence holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

DuoTrav® 40 micrograms/mL + 5mg/mL eye drops, solution; PL 18799/4113

Leaflet date: 05.03.2026

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DuoTrav is the registered trademark of Novartis AG.

For any information about this medicine, please contact the Product Licence Holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.
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