

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

This medicine is dispensed with a doctor's prescription only

DuoTrav®
Eye Drops (Solution)

Composition:

Active ingredients:
Travoprost 40 mcg/mL
Timolol as maleate 5 mg/mL

For the list of inactive ingredients in the preparation see section 6 - "Further information" and section 2 - "Important information regarding some of the ingredients of the medicine".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

Keep this leaflet; you may need to read it again.

This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

To reduce intraocular pressure in cases of open-angle glaucoma or intraocular hypertension that are insufficiently responsive to topical beta blockers or prostaglandin analogs.

Therapeutic group:

Travoprost - prostaglandin analog, which works by increasing the outflow of aqueous fluid from the eye, thereby lowering ocular pressure.

Timolol (as maleate) - beta blocker, which works by reducing the production of fluid within the eye.

The two substances work together to reduce pressure within the eye.

2. BEFORE USING THE MEDICINE

Do not use this medicine if:

- You are sensitive (allergic) to travoprost, prostaglandins, timolol, beta blockers or to any of the other ingredients of the medicine (as detailed in section 6).
- You are breastfeeding.
- You are suffering, or have suffered in the past, from breathing problems, such as asthma or severe chronic bronchitis (a severe lung disease that may cause wheezing, breathing difficulties and/or persistent cough) or other breathing problems.
- You suffer from severe hay fever.
- You have a slow heart rate, heart failure or arrhythmia (irregular heart rate).
- You suffer from cloudiness of the surface of the eye.

If any of these conditions apply to you, consult the doctor.

Special warnings regarding the use of the medicine

Before treatment with DuoTrav, tell the doctor if you are suffering, or have suffered in the past, from -

- o Coronary heart disease (symptoms may include tightness or pain in the chest, shortness of breath or choking), heart failure, low blood pressure.
- o Heart rhythm disorder, such as a slow heart rate.
- o Breathing problems, asthma or chronic obstructive pulmonary disease.
- o Impaired blood flow (such as Raynaud's disease or Raynaud's syndrome).
- o Diabetes (as timolol may mask signs and symptoms of low blood sugar).
- o Overactive thyroid (as timolol may mask signs and symptoms of thyroid disease).
- o Myasthenia gravis (chronic neuromuscular weakness).
- o Cataract surgery.
- o Eye inflammation.
- If you are due to undergo any surgery, inform the doctor that you are using DuoTrav, since timolol may change the effect of certain medicines used during anaesthesia.
- If you experience any severe allergic reaction (skin rash, redness and itchiness in the eye) when using DuoTrav, regardless of the cause, treatment with adrenalin may be less effective. Therefore, when receiving any other treatment, it is important that you tell the doctor that you are using DuoTrav.

DuoTrav may change the color of the iris (the colored part of the eye). This change may be irreversible.

DuoTrav may increase the length, thickness, color and/or number of eye lashes, and can cause unusual hair growth on the eyelids. Travoprost may be absorbed through the skin and therefore should not be used by women who are pregnant or are trying to become pregnant. If the medicine comes into contact with the skin, it should be rinsed off immediately.

Children and adolescents:

DuoTrav is not intended for use in children and adolescents under 18 years of age.

Drug interactions

DuoTrav can affect or be affected by other medicines you use (including other eye drops for glaucoma treatment).

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular, if you are taking or planning to take:

- Medicines to lower blood pressure
- Medicines for the heart including quinidine (used to treat heart problems and certain types of malaria)
- Preparations to treat diabetes
- Antidepressants: fluoxetine or paroxetine

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you are pregnant or are planning a pregnancy, consult the doctor before using this medicine.

Do not use DuoTrav during pregnancy, unless the doctor thinks it is necessary.

If you are of child-bearing age, use adequate contraceptives during use of DuoTrav.

Do not use DuoTrav if you are breastfeeding. DuoTrav may pass into breast milk.

Driving and using machines

Use of DuoTrav may cause blurred vision for some time after use. DuoTrav may cause hallucinations, dizziness, nervousness or fatigue in some patients.

Do not drive or operate machinery until each one of these effects have passed.

Important information regarding some of the ingredients of the medicine

DuoTrav contains hydrogenated castor oil and 7.5 mg/ml propylene glycol, which may cause reaction and irritation of the skin.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

The dosage and the treatment regimen will be determined by the doctor only.

The usual dosage is generally: One drop in the treated eye, once a day (in the morning or evening).

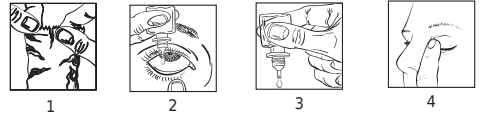
Make sure to use at the same time every day.

Only use DuoTrav in both eyes if the doctor has instructed you to do so. Use DuoTrav as eye drops only.

Do not exceed the recommended dose.

Do not swallow! This medicine is intended for external use only.

Direction for use:



- Immediately before using the bottle for the first time, tear off the over-wrap to open (Figure 1), remove the bottle and record the opening date on the label.
- Make sure that you have a mirror close by.
- To prevent contamination, do not allow the tip of the bottle to come into contact with any surface (including the eye itself). Keep the bottle tightly closed.
- The bottle of drops may not be full; this is meant to allow better control over the drip rate.
- How to use the drops: First, wash your hands. Twist off the cap. Hold the bottle, pointing downwards, between your thumb and index finger (Figure 3). Tilt your head back. Using your index finger, pull your lower lid downward to create a kind of "pocket" (Figure 2). Bring the bottle close to the eye; use a mirror if it helps. Drip the medicine gently, to allow for release of one drop of DuoTrav, into the "pocket" that has been formed (Figure 2). Close your eyes gently. Do not blink. Leave your eyes closed for 2 minutes.
- In addition to the instructions above - immediately after instilling the drops into the eye, press on the inner corner of the eye using your middle finger (Figure 4). Continue applying pressure for 2 minutes after instilling into the eye. This action helps avoid the absorption of the medicine into the body thus helping to prevent side effects.
- If you didn't succeed in instilling into the eye - try again.
- If you have to use DuoTrav in both eyes, repeat the above steps for the other eye.
- Close the bottle tightly immediately after use.
- After using the medicine, wash your hands thoroughly in order to wash off remnants of the medicine.
- In order to avoid spread of infection, do not use the same bottle of medicine for more than one person. Do not open the over-wrap until you need to use the bottle.

Use DuoTrav for the amount of time your doctor has instructed you to.

If you accidentally used a higher dosage, rinse the eye with lukewarm water. Do not instill more drops into the eye until time for the next dose.

If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take this medicine at the required time, take the next dose at the usual time and consult the doctor. Do not take a double dose to compensate for the forgotten dose. Do not exceed the dosage of one drop daily per treated eye(s).

Adhere to the treatment regimen recommended by the doctor. Even if there is an improvement in your condition, do not stop taking the medicine without consulting the doctor.

If you stop taking the medicine without consulting your doctor, this may lead to uncontrolled intraocular pressure, which could lead to loss of sight.

If you are using other eye drops in addition to DuoTrav, wait at least 5 minutes between the application of DuoTrav and other eye drops.

If you are wearing soft contact lenses, do not use the drops while wearing the lenses. Wait 15 minutes after using the drops before putting back the lenses.

Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of DuoTrav may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

You will usually be able to continue using the medicine, unless the effects are severe. If you are concerned, refer to the doctor or pharmacist. Do not stop using the medicine without consulting the doctor.

Very common side effects - side effects that occur in more than one user in ten:

Effects in the eye

Eye redness.

Common side effects - effects that occur in 1-10 users in 100:

Effects in the eye

Inflammation with damage to the surface of the eye, eye pain, blurred vision, visual disturbances, dry eyes, eye itching, eye discomfort, signs and symptoms of eye irritation (such as tingling and burning sensations in the eye).

Uncommon side effects - effects that occur in 1-10 users in 1,000:

Effects in the eye

Inflammation of the surface of the eye, inflammation of the eyelid, swelling of the conjunctiva, increased growth of eyelashes, inflammation of the iris, eye inflammation, sensitivity to light, vision impairment, tired eyes, eye allergy, eye swelling, increased tear production, eyelid redness, eyelid discoloration, skin darkening (around the eye).

General effects

Allergic reactions to the active ingredient, dizziness, headaches, increased or lowered blood pressure, shortness of breath, excessive hair growth, postnasal drip, skin inflammation and itching, decreased heart rate.

Rare side effects - effects that occur in 1-10 users in 10,000:

Effects in the eye

Thinning of the surface of the eye, inflammation of the eyelid glands, rupture of blood vessels in the eye, crusty layer on the eyelid, irregular position of the eyelashes, irregular growth of eyelashes.

General effects

Nervousness, irregular heart rate, hair loss, voice disorders, breathing difficulty, cough, throat irritation, urticaria, abnormal liver function test results, skin discoloration, thirst, tiredness, discomfort in the inner part of the nose, dark urine, pains in hands and legs.

Side effects of unknown frequency (effects whose frequency has not been determined yet):

Effects in the eye

Drooping eyelids (causes the eyes to be partially shut), sunken eyes (the eyes look more sunken), change in the color of the iris (the colored part of the eye).

General effects

Rash, heart failure, chest pains, stroke, fainting, depression, asthma, increased heart rate, numbness or tingling sensation, palpitations, swelling in lower limbs, bad taste in the mouth.

In addition;

DuoTrav contains a combination of two active ingredients, travoprost and timolol. Like other eye medicines, travoprost and timolol (beta blocker) are absorbed into the blood. This can cause side effects similar to those that can be seen with oral or intravenous administration of beta blocker medicines. The frequency of these side effects is lower following use in eyes as compared with oral or intravenous administration.

The side effects listed below include reactions observed upon treatment with beta blocker medicines when administered for the treatment of eye effects, or reactions observed upon administration of travoprost alone:

Effects in the eye

Eyelid inflammation, keratitis, detachment of the layer under the retina containing blood vessels following filtration surgery, which might result in visual disturbances, reduced corneal sensitivity, corneal erosion (damage to the front layer of the eyeball), double vision, discharge from the eye, swelling around the eye, eyelid itching, outward turning of the eyelid with redness, irritation and excess tearing, blurred vision (signs of cloudiness on the lenses of the eye), inflammation of part of the eye (uvea), eyelid eczema, halo vision, decreased eye sensation, pigmentation inside the eye, dilated pupils, change in eyelash color, change in eyelash texture, abnormal field of vision.

General effects

Ear and labyrinth (inner ear) disorders: dizziness with spinning sensation, ringing in the ears.

Heart and blood vessels: slow heart rate, palpitations, edema (fluid retention), change in heartbeat (rhythm or speed), heart failure (a heart disease accompanied by shortness of breath and swelling of the feet and legs due to fluid retention), a certain type of heart rhythm disturbance, heart attack, low blood pressure, Raynaud's effect, cold hands and legs, reduced blood supply to the brain.

Airways: narrowing of the airways in the lungs (mostly in patients with pre-existing disease), runny nose or nasal congestion, sneezing (due to allergy), difficulty breathing, nose bleed, dry nose.

Nervous system and general effects: difficulty sleeping (insomnia), nightmares, memory loss, hallucinations, reduced strength and energy, anxiety (excessive emotional stress).

Gastrointestinal system: taste disorders, nausea, indigestion, diarrhea, dry mouth, abdominal pain, vomiting and constipation.

Allergy: increase in allergy symptoms, general allergic reactions including swelling under the skin, which can occur in areas such as the face and limbs and cause obstruction of the airways, which can cause difficulty in swallowing or breathing, generalized or local rash, itching, sudden, severe, life-threatening allergic reaction.

Skin: skin rash with a white-silvery appearance (psoriasisiform rash) or aggravated psoriasis, skin peeling, unusual hair texture, skin inflammation accompanied by a red, itchy rash, hair discoloration, eyelash loss, itching, unusual hair growth, skin redness.

Muscles: increased signs and symptoms of myasthenia gravis (a muscle disorder), abnormal sensations such as prickling, muscles weakness/tiredness, muscle pain not due to physical exercise, joint pain.

Kidney and urinary system disturbances: difficulty and pain upon passing urine, urinary incontinence.

Reproductive system: impotence, decreased libido.

Metabolism: low blood sugar levels, increased prostate cancer markers.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il), that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine should be kept in a safe place out of the reach and sight of children and/ or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package/label. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Can be used for up to 4 weeks after first opening, in order to prevent risk of infections. Each time you start using a new bottle, record the opening date on the label and carton.
- To help protect the environment, consult the pharmacist regarding how to dispose of medicines that are no longer in use.

6. FURTHER INFORMATION

In addition to the active ingredients, the medicine also contains: Propylene glycol, boric acid, mannitol, sodium chloride, polyoxyethylene hydrogenated, Castor oil 40 (HCO-40), Polyquaterium-1 solution (equivalent to Polyquaterium-1), hydrochloric acid and/or sodium hydroxide (for pH adjustment), purified water.

What the medicine looks like and the contents of the package

DuoTrav is a clear, colorless solution provided in a plastic 2.5 mL bottle with a screw cap. The bottle is packaged in an aluminum wrapper.

Registration Holder and Importer and its address: Novartis Israel Ltd., P.O.B 7126, Tel Aviv.

Revised in December 2020

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 144 33 31764