

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

PrDUOTRAV® PQ
travoprost and timolol ophthalmic solution
with POLYQUAD® as preservative

Read this carefully before you start taking PrDUOTRAV® PQ and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about DUOTRAV PQ.

What is DUOTRAV PQ used for?

DUOTRAV PQ is used to decrease high pressure in the eye in patients with the following conditions:

- Open-angle glaucoma
- Ocular hypertension

High pressure in the eye(s). Your eyeballs contain a clear, watery liquid which feeds the inside of the eye. Liquid is always emptying out of the eye, and more liquid is always being produced. If the eye fills up faster than it empties, the pressure inside the eye builds up. If it gets too high, it can damage your sight.

How does DUOTRAV PQ work?

DUOTRAV PQ decreases the pressure in your eye through the action of travoprost (a prostaglandin analogue) and timolol (a beta-blocker). Travoprost increases the flow of fluid out of your eye. Timolol reduces the amount of fluid produced by your eye.

What are the ingredients in DUOTRAV PQ?

Medicinal ingredients: travoprost and timolol (as timolol maleate).

Non-medicinal ingredients: boric acid, mannitol, polyoxyethylene hydrogenated castor oil 40, polyquaternium-1 (POLYQUAD), propylene glycol, purified water and sodium chloride. May also contain hydrochloric acid and/or sodium hydroxide to adjust pH.

DUOTRAV PQ comes in the following dosage forms:

Solution: travoprost 0.004% w/v and timolol 0.5% w/v (as timolol maleate)

Do not use DUOTRAV PQ if you:

- Have, or have ever had, an unusual or allergic reaction to this drug or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container.
- Are pregnant or planning to become pregnant.
- Have, or have had, a lung condition. These can include asthma or chronic obstructive pulmonary disease (COPD).
- Have certain heart conditions, heart disease, or heart problems, such as slow heartbeat, heart failure, or heart rhythm disorder (irregular heartbeats).

To help avoid side effects and ensure proper use, talk to your healthcare professional

before you take DUOTRAV PQ. Talk about any health conditions or problems you may have, including if you:

- Have or have had diabetes or low blood sugar (hypoglycemia).
- Have or have had thyroid problems. This can include a condition called thyrotoxicosis.
- Have or have had kidney problems.
- Have muscle weakness or have a condition causing muscle weakness called myasthenia gravis.
- Have heart disease, low blood pressure, circulation problems such as Raynaud's syndrome or problems with blood circulation to the brain.
- Are breastfeeding or planning to breastfeed.
- Are planning to have surgery.
- Have had a severe allergic reaction.
- Have had cataract surgery.
- Have had a filtration procedure (a type of eye surgery). You may develop detachment of the internal layer of the eye.
- Have or have had an eye injury.
- Have or have had eye inflammation (iritis and/or uveitis).
- Have or have had distorted vision that is making things look blurry and colors look washed out. This can include a condition called macular edema.
- Are using other medicines called beta-blockers or prostaglandin analogues.

Other warnings you should know about:

Talk to your doctor if you develop an eye or eyelid infection while taking DUOTRAV PQ.

Not recommended to individuals under 18 years of age.

Pressure in your eye(s): Your doctor should check the pressure in your eye(s) regularly.

Eye color and eyelash changes: Using DUOTRAV PQ may cause your eye color to become more brown or cause your eyelashes to become thicker, longer and darker. These changes may be permanent. If you are using DUOTRAV PQ in only one eye, your two eyes may look different. Your doctor should examine you regularly to make sure your medication is working and look for changes in eye colour. Your doctor may stop treatment if needed.

Eyelid skin darkening: Using DUOTRAV PQ may cause darkening of your eyelid skin.

Contact lens wear: Do not wear contact lenses while applying DUOTRAV PQ. Remove your contact lenses before applying DUOTRAV PQ and wait at least 15 minutes before putting them back in.

Skin contact: DUOTRAV PQ contains propylene glycol and polyoxyethylene hydrogenated castor oil, which can cause skin reactions. Avoid accidental contact with your skin. Wipe up any spills and rinse the contacted areas with water.

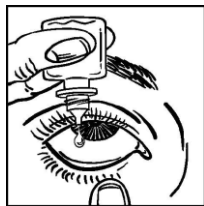
Driving and using machines: DUOTRAV PQ may cause you to become drowsy or your vision may become blurry for some time. If any of these happen to you, wait until they go away before driving or using machines.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

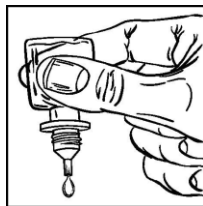
The following may interact with DUOTRAV PQ:

- Digitalis, a medicine used to treat congestive heart failure and heart rhythm problems.
- Calcium antagonists, used to treat high blood pressure.
- Catecholamine-depleting drugs, e.g. reserpine, used to treat high blood pressure.
- Quinidine, an antiarrhythmic used to treat heart conditions and some types of malaria.
- Injectable epinephrine, used to treat severe allergic reactions.
- Central nervous system depressants, used to treat insomnia, anxiety, panic attacks and seizures.
- Tricyclic antidepressants, used to treat depression.
- Other beta-blocking drugs, used to decrease blood pressure.

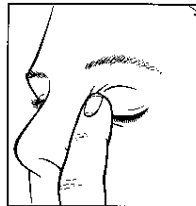
How to take DUOTRAV PQ:



1



2



3

- Get the DUOTRAV PQ bottle and a mirror.
- Wash your hands.
- Open the bottle being careful not to touch the dropper tip.
- 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 there (see picture 1).
- Bring the bottle tip close to the eye. Use the mirror if it helps.
- Don't touch your eye or eyelid, surrounding areas or other surfaces with the bottle tip. It could contaminate the drops.
- Gently squeeze the bottle to release one drop of DUOTRAV PQ (see picture 2).
- After using DUOTRAV PQ, press a finger into the corner of your eye, by the nose (see picture 3). This helps to stop DUOTRAV PQ from getting into the rest of the body.
- If a drop misses your eye, wipe with a tissue and try again.
- If you take drops in both eyes, repeat the steps for your other eye.
- Close the bottle cap firmly immediately after use.
- Wash your hands after use.

If you are using more than one eye drop, wait at least 5 minutes between using DUOTRAV PQ and the other drop(s).

Usual dose:

Use one drop of DUOTRAV PQ in the affected eye(s) once daily.
Use DUOTRAV PQ either in the morning or in the evening.

Overdose:

If you use more DUOTRAV PQ than you should, rinse it all out with warm tap water. Using too many drops may cause your eyes to become red and irritated. Do not put in any more drops until it's time for your next regular dose.

If you accidentally ingest DUOTRAV PQ, contact your doctor or pharmacist for advice.

If you think you have used too much DUOTRAV PQ, contact a healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose, wait until it is time for your next dose. Do not double dose to make up for a missed dose.

What are possible side effects from using DUOTRAV PQ?

These are not all the possible side effects you may feel when taking DUOTRAV PQ. If you experience any side effects not listed here, contact your healthcare professional.

Side effects in the eye(s) include:

- Redness.
- Itching.
- Dryness.
- Pain.
- Sensitivity to light.
- Abnormal sensation in eye or other eye irritations.
- Blurred vision.
- Temporary reduction of vision.
- Tearing.
- Growth of eyelashes and eyebrows hair.
- Abnormally positioned eyelashes.
- Eye swelling.
- Discomfort (burning and stinging).
- Changes in vision.
- Itching, swollen, heavy, painful or irritated eyelids.
- Inflammation of the eyelid glands.
- Increased eye pressure.
- Eyelid crusting.
- Sunken eyes (eyes appear more inset).
- Changes in the color of the iris (colored part of the eye).
- Skin darkening (around the eye).

Side effects in other areas of the body include:

- Headache.
- Postnasal drip.
- Thirst, cough or throat pain or irritation.
- A change in blood pressure or heart rate.
- Disturbance in attention.
- Dizziness.
- Nervousness.
- Seeing, feeling or hearing things that are not there (hallucination).
- Depression.
- Skin infection or irritation, skin reaction, skin redness.
- Ear infections.
- Pain in arms or legs.
- Shortness of breath, difficulty breathing
- Fatigue.
- Discomfort inside the nose.
- A change in urine color.
- Bad taste in the mouth.
- Strained talking or swelling in the limbs.
- Rash.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNKNOWN Allergic reaction: swelling or inflammation of the eye, trouble breathing			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store between 2°C and 25°C. No refrigeration is required.

Do not use this medicine after the expiry date on the bottle or carton.
Discard 120 days after first opening.
Keep out of reach and sight of children.

If you want more information about DUOTRAV PQ:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); the manufacturer's website www.novartis.ca, or by calling 1-800-363-8883.

This leaflet was prepared by Novartis Pharmaceuticals Canada Inc.

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