

DUOTRAV® Eye Drops

travoprost 0.004% and timolol 0.5%

Consumer Medicine Information

What is in this Leaflet

This leaflet answers some common questions about DUOTRAV® Eye Drops. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using DUOTRAV® Eye Drops against the benefits it is expected to have for you.

If you have any concerns about using this medicine ask your doctor or pharmacist.

Keep this leaflet with your medicine. You may need to read it again.

What are DUOTRAV® Eye Drops used for?

DUOTRAV® Eye Drops are used to lower pressure in the eye and to treat glaucoma. Glaucoma is a condition in which the pressure of the fluid in the eye may be high. However, some people with glaucoma may have normal eye pressure. Also, some people with raised eye pressure may not have glaucoma.

DUOTRAV® Eye Drops contain two active ingredients, travoprost and timolol, that lower the pressure in the eye. Travoprost belongs to a family of medicines known as 'prostaglandins'. Timolol belongs to a family of medicines known as 'beta-blockers'.

DUOTRAV® Eye Drops lowers the pressure within the eye by two processes. It improves the flow of fluid from your eye(s) (travoprost) and decreases the production of fluid (timolol).

Although DUOTRAV® Eye Drops helps to control your glaucoma it does not cure it.

For more information about glaucoma contact Glaucoma Australia Inc. on 1800 500 880 or www.glaucoma.org.au

Your doctor may have prescribed DUOTRAV® Eye Drops for another reason. Ask your doctor if you have any questions about why DUOTRAV® Eye Drops have been prescribed for you.

DUOTRAV® Eye Drops are not addictive.

Before you use DUOTRAV® Eye Drops

When you must not use it

Do not use DUOTRAV® Eye Drops if you have an allergy to:

- **DUOTRAV® Eye Drops, travoprost, timolol or any of the ingredients listed at the end of this leaflet**
- **any other 'prostaglandin' or 'beta-blocker' medicine.**

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not use DUOTRAV® Eye Drops if:

- **you have asthma, or a history of asthma, chronic obstructive lung disease (emphysema), or other breathing problems**
- **you have certain heart conditions, such as a very slow heart rate, an irregular heart beat or heart failure.**

If you are not sure whether you should start using DUOTRAV® Eye Drops, talk to your doctor.

Do not use DUOTRAV® Eye Drops if you are wearing contact lenses. The preservative in DUOTRAV® Eye Drops (benzalkonium chloride) may be deposited in soft contact lenses. You can put your contact lenses into your eyes 15 minutes after you have used DUOTRAV® Eye Drops.

Do not use DUOTRAV® Eye Drops in a child.

The safety and effectiveness of DUOTRAV® Eye Drops in children have not been established.

Do not use DUOTRAV® Eye Drops after the expiry date printed on the pack or if the foil overwrap pouch appears damaged in any way (unless that the foil overwrap pouch has been removed by your pharmacist).

If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to use it

Tell your doctor if:

1. **you have an allergy to DUOTRAV® Eye Drops or any of the ingredients listed at the end of this leaflet**
2. **you are pregnant or intend to become pregnant.** Your doctor will discuss the possible risks and benefits of using DUOTRAV® Eye Drops during pregnancy.
3. **you are breast-feeding or intend to breast-feed.** Your doctor will discuss the possible risks and benefits of using DUOTRAV® Eye Drops when breast-feeding.
4. **you have or have had any of the following medical conditions:**
 - heart disease
 - lung disease
 - any other types of glaucoma
 - diabetes
 - myasthenia gravis
 - hyperthyroidism
5. **you are already using another beta-blocker eye drop and/or another prostaglandin eye drop.** The use of two beta-blocker eye drops and/or prostaglandin eye drops at the same time is not recommended.
6. **you have a history of allergic problems, including eczema, hives or hay fever.**
7. **you have an allergy to any other medicines or any other substances, such as foods, preservatives or dyes.**

If you have not told your doctor about any of the above, tell them before you use DUOTRAV® Eye Drops.

Using other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and DUOTRAV® Eye Drops may interfere with each other. These include:

- certain medicines used to treat high blood pressure or heart conditions, including beta-blockers, calcium channel blockers or digoxin
- certain medicines used to treat irregular heart beats such as amiodarone and quinidine
- narcotics such as morphine used to treat moderate to severe pain
- medicines used to treat diabetes or high blood sugar
- other eye drops that contain a beta-blocker or a prostaglandin.

These medicines may be affected by DUOTRAV® Eye Drops, or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while using DUOTRAV® Eye Drops.

How to use DUOTRAV® Eye Drops

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

If you are being changed from one eye drop to another, follow your doctor's instructions carefully as to when to stop the old drops and when to start the new drops.

How much to use

Instil **one drop** of Duotrav once daily at about the same time each day in the conjunctival sac of the affected eye(s).

Your doctor will tell you how many drops you need to use each day. These dosing instructions will be printed on the label your pharmacist puts on the bottle or carton.

How to use it

You may find it easier to put drops in your eye while you are sitting or lying down.

Do not use a bottle of DUOTRAV® Eye Drops if the foil overwrap pouch appears to be damaged or tampered with. If it is, do not use the bottle and return it to your pharmacist. Unless that the foil overwrap pouch has been removed by your pharmacist.

If you are wearing contact lenses, remove them before putting the drops in your eye.

Follow these steps to use DUOTRAV® Eye Drops:

1. Wash your hands well with soap and water.
2. Immediately before using a bottle for the first time, tear-open the foil overwrap pouch (if present) and take the bottle out (see Diagram 1).

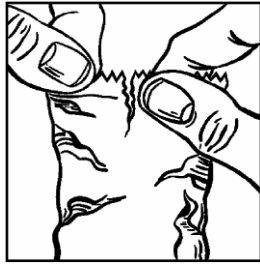


Diagram 1

3. Remove the cap from the bottle.
4. Hold the bottle upside down in one hand between your thumb and first (index) finger. It will not leak (see Diagram 2).

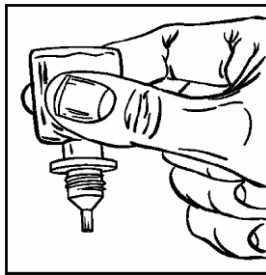


Diagram 2

5. Using your other hand, gently pull down your lower eyelid to form a pouch.
6. Tilt your head back and look up.
7. Place the tip of the bottle close to your lower eyelid. Do not let it touch your eye.
8. Release one drop into the pouch formed between your eye and eyelid by gently squeezing the bottle (see Diagram 3).

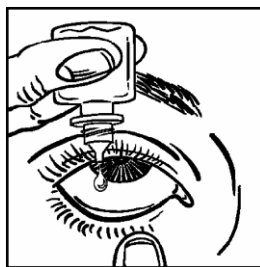


Diagram 3

9. Close your eye and keep it closed. Do not blink or rub your eye. With the eye closed place your index finger against the inside corner of your eye and press against your nose for a couple of minutes.
10. If necessary repeat the above steps 3-8 for your other eye.
11. Replace the cap on the bottle, closing it tightly.
12. Wash your hands again with soap and water to remove any residue.

Wait at least 15 minutes before inserting your contact lenses.

You may feel a slight burning sensation in the eye shortly after using the eye drops. If this persists, or is very uncomfortable, contact your doctor or pharmacist.

Be careful not to touch the dropper tip against your eye, eyelid or anything else to avoid contaminating the eye drops. Contaminated eye drops may give you an eye infection.

After using DUOTRAV® Eye Drops wait at least 5 minutes before putting any other eye drops in your eye(s).

If you are unsure about when, or how, to stop using DUOTRAV® Eye Drops you should talk to your doctor.

When to use it

Use DUOTRAV® Eye Drops once a day, at about the same time each day, unless your doctor tells you otherwise.

Using your eye drops at the same time each day will have the best effect on your eye pressure. It will also help you remember when to use the eye drops.

How long to use it

DUOTRAV® Eye Drops helps control your condition but does not cure it. Therefore DUOTRAV® Eye Drops must be used every day. Continue using DUOTRAV® Eye Drops for as long as your doctor prescribes.

If you forget to use it

If you miss a dose, skip the dose you missed and take your next dose when you are meant to.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

Do not take a double dose to make up for the dose that you missed.

If you have trouble remembering to use your eye drops, ask your pharmacist for some hints.

If you use too much (overdose)

If you think that you or someone else has swallowed any or all of the contents of DUOTRAV® Eye Drops, or used too many drops, immediately telephone your doctor or the Poisons Information Centre (in Australia call 13 1126; in New Zealand call 0800 POISON or 0800 764 766) for advice or go to Accident & Emergency at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.

If DUOTRAV® Eye Drops is accidentally swallowed, or if you use too many drops, you may feel light-headed or dizzy, you may faint, have a very slow pulse rate, or have wheezing or difficulty breathing. Other effects include nausea, abdominal pain, fatigue, hot flushes and sweating.

While you are using DUOTRAV® Eye Drops

Things you must do

Have your eye pressure checked when your specialist says, to make sure DUOTRAV® Eye Drops is working.

If you develop an eye infection, receive an eye injury, or have eye surgery tell your doctor. Your doctor may tell you to use a new bottle of DUOTRAV® Eye Drops because of possible contamination of the old one, or may advise you to stop treatment with DUOTRAV® Eye Drops.

If you become pregnant while using DUOTRAV® Eye Drops, tell your doctor.

If you are about to be started on any new medicine tell your doctor and pharmacist that you are using DUOTRAV® Eye Drops.

Things you must not do

Do not give DUOTRAV® Eye Drops to anyone else, even if they have the same condition as you.

Do not stop using DUOTRAV® Eye Drops without first talking to your doctor. If you stop using your eye drops, your eye pressures may rise again and damage to your eye may occur.

Things to be careful of

Be careful driving or operating machinery until you know how DUOTRAV® Eye Drops affects you.

DUOTRAV® Eye Drops may cause temporary blurred vision or dizziness after using the drops.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using DUOTRAV® Eye Drops. DUOTRAV® Eye Drops helps most people with elevated eye pressure and glaucoma, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

While using DUOTRAV® Eye Drops you may experience some or all of the following reactions in your eye:

- abnormal sensation in the eye or other eye irritations
- alterations in vision, blurred vision or temporary reduction of vision
- dryness
- swelling of the eye
- itching
- pain or discomfort
- redness
- sensitivity to light
- tearing

You may also experience itching, swollen, heavy, painful or irritated eyelids and growth of eyelashes.

You may also experience reactions in other areas of your body, including:

- headache
- pain in an extremity
- a change in blood pressure or heart rate

- disturbance in attention
- dizziness
- nervousness
- skin infection or irritation
- skin redness
- ear infections
- shortness of breath/difficulty breathing
- laryngitis
- postnasal drip
- thirst, cough or throat irritation
- a change in liver enzymes
- a change in urine colour

DUOTRAV® Eye Drops may gradually change the colour of the eye; this is due to an increase in pigment within the iris (coloured portion of the eye). This change in eye colour is most frequently seen in eyes with mixed colours (e.g. blue brown, grey brown); however, it may also occur with single coloured eyes. This change in eye colour may be permanent.

These are usually mild side effects of DUOTRAV® Eye Drops.

Tell your doctor immediately or go to Accident & Emergency at your nearest hospital if you notice any of the following:

- fast or irregular heart beats, also called palpitations
- dizziness and light-headedness, which may be due to low blood pressure
- skin rash, itching
- swelling of the hands, feet, ankles or legs

These may be serious side effects. You may need urgent medical attention.

Serious side effects are rare.

If any of the following happen, stop using DUOTRAV® Eye Drops and tell your doctor immediately or go to Accident & Emergency at your nearest hospital:

- wheezing, difficulty in breathing
- shortness of breath
- very slow pulse, chest pain
- fainting
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in breathing or swallowing
- severe and sudden onset of pinkish, itchy swellings on the skin, also called hives or nettle rash

These are serious side effects. You may need urgent medical attention. All of these side effects are rare.

Other side effects not listed may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible side effects. It is unlikely that you will experience any of them.

After using DUOTRAV® Eye Drops

Storage

Keep your eye drops in a cool place where the temperature stays below 25°C.

Do not leave it in the car or on the window sill. Do not carry the eye drops in pockets of your clothes. Heat can destroy some medicines.

Keep it where children cannot reach it. A locked cupboard at least one and a half metres above the ground is a good place to store medicines.

Do not leave the screw cap off the bottle for any length of time, to avoid contaminating the eye drops.

Disposal

Write the date on the bottle when you open the eye drops and throw out any remaining solution after four weeks.

Eye drops contain a preservative which helps prevent germs growing in the solution for the first four weeks after opening the bottle. After this time there is a greater risk that the drops may become contaminated and cause an eye infection. A new bottle should be opened.

If your doctor tells you to stop using the eye drops or they have passed their expiry date, ask your pharmacist what to do with any remaining solution.

Product description

What it looks like

DUOTRAV® Eye Drops comes in an oval dropper bottle (DROP-TAINER®) with screw cap containing 2.5 mL of eye drop solution. The bottle is covered in a foil overwrap pouch, although this may have been removed by your pharmacist.

Ingredients

Active ingredients

- travoprost 0.004%
- timolol maleate, equivalent to timolol 0.5%

Other ingredients:

- benzalkonium chloride (0.15 mg/mL) as preservative
- castor oil - ethoxylated hydrogenated
- disodium edetate
- boric acid
- trometamol
- mannitol and
- purified water

The pH of the solution may be adjusted with hydrochloric acid.

Supplier

DUOTRAV® Eye Drops are supplied in Australia by:
Alcon Laboratories (Australia) Pty Ltd
25 Frenchs Forest Road East
FRENCHS FOREST NSW 2086

DUOTRAV® Eye Drops are distributed in New Zealand by:
Alcon New Zealand Limited
c/o Pharmaco (NZ) Limited

4 Fisher Crescent
Mt Wellington Auckland

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