

DUOTRAV[®] Eye Drops

travoprost 0.004% and timolol 0.5%

Consumer Medicine Information

What is in this Leaflet

Read this leaflet carefully before you start to use DuoTrav Eye Drops.

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.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine.

You can also download the most up to date leaflet in Australia from www.novartis.com.au and www.medsafe.govt.nz in New Zealand.

The updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you using DuoTrav against the benefits they expect it will 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 DUOTRAV is 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 lower the pressure within the eye by two processes. They improve the flow of fluid from your eye(s) (travoprost) and decrease the production of fluid (timolol). Although DuoTrav Eye Drops help to control your glaucoma they do not cure it.

Before prescribing DuoTrav Eye Drops for you, your doctor will have examined the eye and decided that DuoTrav Eye Drops is the right medicine.

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.

For more information about glaucoma contact Glaucoma Australia on 1800 500 880 or

Glaucoma NZ on 0800
GLAUCOMA or 0800 452 826.

Use in children

This medicine is not recommended in children.

The safety and effectiveness of DuoTrav Eye Drops has not been established in children.

Before you use DuoTrav

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 are a pregnant woman or intend to become pregnant.
DuoTrav Eye Drops are not recommended in pregnancy.
- 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.**

Do not use this medicine if:

- the foil overwrap pouch appears damaged in any way (it is possible that the foil overwrap pouch may have been removed by your pharmacist)
- the bottle/packaging shows signs of tampering
- the expiry date on the bottle/carton has passed. If you use this medicine after the expiry date has passed, it may not work as well.

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

Do not use DuoTrav Eye Drops if you are wearing contact lenses.

You can put your contact lenses into your eyes 15 minutes after you have used DuoTrav Eye Drops.

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

Before you start to use it

Tell your doctor if:

You have an allergy to any other medicines or any other substances, such as foods, preservatives or dyes.

You have a history of allergic problems, including eczema, hives or hay fever.

You are breastfeeding or intend to breastfeed.

Your doctor will discuss the possible risks and benefits of using DuoTrav Eye Drops when breastfeeding.

You have or have had any of the following medical conditions:

- heart disease
- lung disease
- circulation disorders such as Raynaud's disease
- any other types of glaucoma
- diabetes
- myasthenia gravis

- hyperthyroidism
- dry eyes or any disease of the cornea.

Tell your doctor if you have any other medical conditions.

Tell your doctor if 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.

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

Using or taking other medicines

Tell your doctor or pharmacist if you are using or 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 heartbeats such as amiodarone and quinidine
- medicines used to treat major depression such as fluoxetine or paroxetine
- monoamine oxidase inhibitors (MAOIs) used to treat depression
- narcotics, such as morphine, used to treat moderate to severe pain
- medicines used to treat diabetes or high blood sugar
- adrenaline used to treat anaphylactic shock (a severe, life threatening, hypersensitivity reaction)
- other eye drops that contain a beta-blocker or a prostaglandin. This is particularly important if

you are currently taking any tablets to treat glaucoma or you are using any other type of eye drops.

Some 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

Carefully follow all directions given to you by your doctor and pharmacist.

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.

If you do not understand the instructions on the carton, ask your doctor or pharmacist for help.

How much to use

The usual dose is one drop of DuoTrav Eye Drops once daily at about the same time each day, in either one or both eyes.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

These dosing instructions will be printed on the label your pharmacist puts on the bottle or carton.

How to use it

It is important to use DuoTrav Eye Drops exactly as your doctor or pharmacist has told you. If you use it less often than you should, it may not work as well and the eye problem

may not improve. Using it more often than you should may not improve the eye problem any faster and may cause increased side effects.

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).

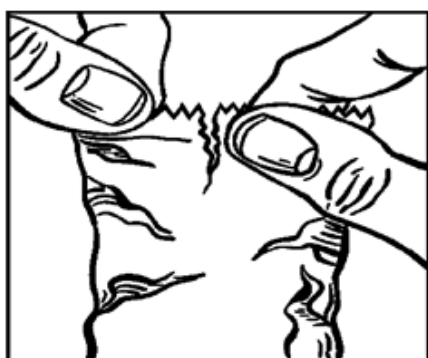


Diagram 1

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).

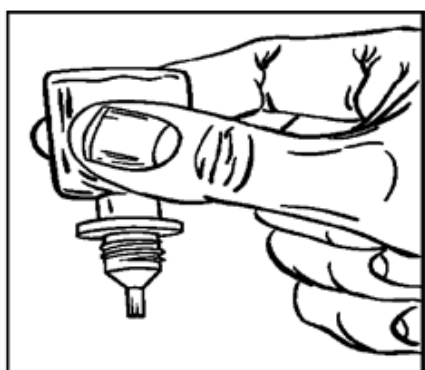


Diagram 2

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).

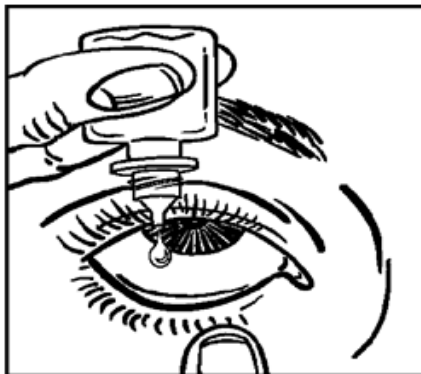


Diagram 3

9. Close your eye and keep it closed. Do not blink or rub your eye.
10. 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. This will help to stop the medicine from draining through the tear duct to the nose and throat, from where it can be absorbed into other parts of your body. This will also reduce the unpleasant taste sensation that some people experience when using these drops.
11. If necessary, repeat the above steps for your other eye.
12. Your eyelids can only hold less than one drop at a time, so it is normal for a small amount of the eye drop to spill onto your cheek. You should wipe away any spillage with a tissue.
13. Replace the cap on the bottle, closing it tightly.
14. 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.

If you have trouble knowing whether you have placed your drops correctly, you may want to store them in the fridge. Some people find it easier to feel the drops in the eye if they are cold.

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

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

Your doctor or pharmacist will tell you how long to use DuoTrav Eye Drops.

DuoTrav Eye Drops help control your condition but do not cure it. Therefore, DuoTrav Eye Drops must be used every day. Continue using DuoTrav Eye Drops for as long as your doctor prescribes.

Do not use DuoTrav Eye Drops longer than your doctor tells you. If you use DuoTrav Eye Drops longer than your doctor or pharmacist tells you, the chance of side effects may increase.

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

If you forget to use it

If you forget to use DuoTrav Eye Drops, you should put the drops that you missed in the eye(s) as soon as you remember and then go back to using them as recommended by your doctor. If it is almost time for the next dose, skip the dose that you missed and continue using them as recommended.

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

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

Using multiple doses may cause unwanted side effects.

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

If you use too much (overdose)

If you accidentally put several drops in your eye(s), immediately rinse your eye(s) with warm water.

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 on 13 11 26 in Australia or the National Poisons Centre in New Zealand on 0080 POISON or 800 764 766 for advice. Alternatively, go to Accident and Emergency at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.

If DuoTrav Eye Drops are 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

Things you must do

Tell all doctors and pharmacists who are treating you are using DuoTrav Eye Drops.

Tell your doctor if, for any reason, you have not used DuoTrav Eye Drops exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change the treatment unnecessarily.

You should have your eye pressure checked when your specialist says, to make sure DuoTrav Eye Drops are 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 immediately.

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:

- let children handle DuoTrav Eye Drops
- stop using DuoTrav Eye Drops without first asking your doctor
- give this medicine to anyone else, even if they appear to have the same condition as you
- use DuoTrav Eye Drops to treat other complaints unless your doctor or pharmacist tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how DuoTrav Eye Drops affect you and your vision.

This medicine may cause temporary blurred vision or other visual disturbances which may affect the ability to drive or use machinery in some people.

If blurred vision occurs when you use your drops, wait until your vision is clear before driving or operating machinery.

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 help 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.

Do not be alarmed by the following list of possible side effects. You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following effects in the eye(s) and the eye area and they worry you. These are usually the most common side effects of your medication. They are usually mild and short-lived:

- redness of eye
- eye pain
- eye discomfort
- alterations in vision, blurred vision or temporary reduction of vision
- dry eyes
- itchy eyes
- eye surface inflammation with surface damage
- eye irritation

You may also experience red, itching, swollen, heavy, painful or irritated eyelids, bleeding, crusty eyelids, inflammation of the eye, sensitivity to light, blurred vision, tired eyes, tearing, corneal erosion, swelling of the eye, double vision, drooping eyelid(s), sunken eyes (eyes appear more inset) and abnormal growth of eyelashes.

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.

DuoTrav Eye Drops may cause changes to your eyelashes such as increased length, thickness and colour.

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

- headache
- a change in blood pressure or heart rate
- skin discolouration (including around the eye)
- abnormal hair growth
- loss of hair
- tiredness
- nervousness
- seeing, feeling or hearing things that are not there (hallucination)
- depression
- numbness
- loss of movement or coordination
- muscular weakness
- confusion or loss of memory
- chest pain
- cough
- asthma
- hoarse or strained voice
- throat irritation
- abnormal taste sensation.

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

- fast or irregular heartbeats, 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 and Emergency at your nearest hospital:

- wheezing, difficulty in breathing
- shortness of breath
- skin rash
- 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 hypersensitivity reactions can be very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

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

After using DuoTrav

Storage

Store DuoTrav Eye Drops in a cool, dry place where the

temperature stays below 25°C. It is not necessary to store DuoTrav Eye Drops in the refrigerator, but it is acceptable if you prefer to instil cold drops.

Do not freeze.

Do not leave DuoTrav Eye Drops in the car, in the bathroom or in other warm, damp places.

Heat and temperature can destroy some medicines.

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

Keep DuoTrav Eye Drops, and all other medicines, in a safe place away from children.

A locked cupboard at least one and a half metres above the ground is a good place to store medicines.

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 the expiry date has passed, ask your pharmacist what to do with any remaining solution.

Product description

What it looks like

DuoTrav Eye Drops is a sterile, isotonic aqueous solution that comes in an oval dropper bottle with a 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

DuoTrav Eye Drops contain the active ingredients:

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

DuoTrav Eye Drops also contain:

- polyquaternium-1 (0.01 mg/mL) as preservative
- castor oil - ethoxylated hydrogenated
- boric acid
- sodium chloride
- propylene glycol
- mannitol
- water-purified.

The pH of the solution may be adjusted with sodium hydroxide and/or hydrochloric acid.

Supplier

This product is supplied in Australia by:

Novartis Pharmaceuticals Australia Pty Limited

ABN 18 004 244 160

54 Waterloo Road

Macquarie Park NSW 2113

Telephone No. 1800 671 203

www.novartis.com.au

This product is supplied in New Zealand by:

Novartis New Zealand Limited

PO Box 99102

Newmarket

Auckland 1149

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Free Phone: 0800 354 335.

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