Travoprost and Timolol maleate

## **Consumer Medicine Information (CMI) summary**

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

## 1. Why am I using DuoTrav?

DuoTrav contains the active ingredients Travoprost and Timolol maleate. It is used to treat certain types of eye conditions such as high pressure inside your eye and open angle glaucoma (an eye condition caused by fluid buildup that damages the optic nerve).

For more information, see Section <u>1. Why am I using DuoTrav?</u> in the full CMI.

### 2. What should I know before I use DuoTrav?

Do not use if you have ever had an allergic reaction to DuoTrav or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use DuoTrav? in the full CMI.

## 3. What if I am taking other medicines?

Some medicines may interfere with DuoTrav and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

### 4. How do I use DuoTrav?

- Put one drop of DuoTrav once daily into the affected eye(s).
- Follow the instructions provided and use DuoTrav until your doctor tells you to stop.

More instructions can be found in Section <u>4. How do I use DuoTrav?</u> in the full CMI.

## 5. What should I know while using DuoTrav?

Things you should do	<ul> <li>Remind any doctor, dentist, pharmacist or specialist you visit that you are using DuoTrav.</li> <li>Remove your soft contact lenses before putting in DuoTrav.</li> <li>Tell your doctor immediately if you notice any signs of an allergic reaction such as skin rash, redness of skin or fever.</li> </ul>
Things you should not do	<ul> <li>Do not stop using this medicine suddenly.</li> <li>Do not use DuoTrav in children.</li> <li>Do not touch the dropper tip with your fingers or to your eye or any other surface.</li> </ul>
Driving or using machines	<ul> <li>DuoTrav may cause temporary blurred vision in some people.</li> <li>Be careful before you drive or use any machines or tools until you know how DuoTrav affects you.</li> </ul>
Looking after your medicine	<ul> <li>Store below 25 °C.</li> <li>Keep it where young children cannot reach it.</li> </ul>

For more information, see Section 5. What should I know while using DuoTrav? in the full CMI.

## 6. Are there any side effects?

Common side effects include redness of the eye(s), eye pain, reduced vision, dry eye, eye irritation, eye swelling, excessive secretion of tears from the eye(s).

# **DuoTrav**®

Eye Drops Solution Active ingredients: Travoprost and Timolol maleate

# **Consumer Medicine Information (CMI)**

This leaflet provides important information about using DuoTrav. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using DuoTrav.

#### Where to find information in this leaflet:

- <u>1. Why am I using DuoTrav?</u>
- 2. What should I know before I use DuoTrav?
- 3. What if I am taking other medicines?
- 4. How do I use DuoTrav?
- 5. What should I know while using DuoTrav?
- 6. Are there any side effects?
- 7. Product details

## 1. Why am I using DuoTrav?

**DuoTrav contains the active ingredients Travoprost and Timolol maleate.** Travoprost belongs to class of drugs called Prostaglandin analogs. Timolol maleate belongs to class of drugs called beta-blockers.

DuoTrav is used to treat certain types of eye conditions such as high pressure inside your eye and open angle glaucoma (an eye condition caused by fluid buildup that damages the optic nerve).

DuoTrav helps to lower the increased eye pressure in two ways. The active ingredient Travoprost helps in increasing the amount of fluid that drains from the eye and Timolol maleate helps to decrease the production of fluid.

## 2. What should I know before I use DuoTrav?

#### Warnings

#### Do not use DuoTrav if:

- you are allergic to Travoprost and Timolol maleate, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine. Symptoms of allergic reaction may include shortness of breath, difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, hives.
- you are pregnant or planning to become pregnant.
- you suffer from any respiratory problems such as asthma (disease of airways) or a history of asthma, or severe chronic obstructive pulmonary disease (serious lung condition caused due to damage to the lungs)
- you have any heart problems such as problems with your heart beat, problems with heart function, any history of heart attack, low blood pressure or any other heart disease.

#### Check with your doctor if you:

- have any problems with your blood vessels such as severe forms of Raynaud's disease (a condition characterized by skin colour changes, affected part feels cold or numb, skin ulcers).
- use any other beta-blocker eye drop and/or another prostaglandin eye drop.
- have diabetes or problems with low blood sugar levels or problems with your thyroid gland.
- suffer from myasthenia gravis (a serious disease that causes muscle weakness along with symptoms such as dropping eyelid, double vision, difficulty in swallowing).
- have a history of allergic problems, e.g. hives or hay fever.
- suffer from any swelling of the eye or any diseases of the eye(s).

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6. Are there any side effects</u>?

#### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

DuoTrav should not be used in pregnancy or in women planning to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

It is not recommended to use DuoTrav while breastfeeding.

## 3. What if I am taking other medicines?

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

# Some medicines may interfere with DuoTrav and affect how it works.

# Tell your doctor if you take any of the following medicines:

- medicines used to treat high blood pressure or heart problems, e.g. beta-blockers (Metoprolol), calcium channel blockers or digoxin, digitalis glycosides
- medicines used to treat irregular heartbeats e.g. amiodarone and quinidine
- fluoxetine or paroxetine, monoamine oxidase inhibitors (MAOIs) medicines used to treat depression
- narcotics e.g. morphine which is used to treat moderate to severe pain

- medicines used to treat severe allergic reaction e.g. adrenaline
- medicines used to treat high blood sugar
- any other eye drops that are similar DuoTrav or other eye drops used in treatment of glaucoma.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect DuoTrav.

# 4. How do I use DuoTrav?

### How much to use

- Follow the instructions provided and use DuoTrav until your doctor tells you to stop.
- Put one drop of DuoTrav once daily at about the same time each day in the affected eye(s).
- Do not put DuoTrav in more than once daily.
- If you are using any other eye drops, use the eye drops at least 5 minutes apart.
- Tell your doctor or pharmacist if you do not understand your dose.

### When to use DuoTrav

• DuoTrav should be used at about the same time each day unless your doctor tells you otherwise.

#### How to use DuoTrav

- Sitting or lying down might make administration of your eye drops process simpler.
- Remove contact lenses if you are wearing them before instilling the eye drops.
- Shake the bottle well prior to use.

#### Follow the steps below to use DuoTrav:

- Wash your hands thoroughly with soap and water.
- Before using a bottle for the first time, tear off the overwrap pouch and take the bottle out (refer diagram 1).



#### Diagram 1

- Remove the cap from the bottle.
- Mix the contents of the bottle by inverting 5 to 10 times.
- Hold the bottle upside down in one hand between your thumb and middle finger (refer diagram 2).



#### Diagram 2

- Tilt your head back, gently pull down the lower eyelid of your eye to form a pouch/pocket.
- Place the tip of the bottle close to your eye. Do not touch the tip to your eye as this may cause injury to the eye.
- Do not touch the dropper tip to eyelid or surrounding areas or any surface to avoid contamination of the dropper tip and solution.
- Release one drop into the pouch/pocket formed between your eye and eyelid by gently tapping or pressing the base of the bottle with your forefinger (refer diagrams 3 and 4).



#### Diagram 3



#### Diagram 4

- Gently close your eye. Do not blink or rub your eye.
- When your eye is closed, place your index finger against the inside corner of your eye and press against your nose for about two minutes. This will help to prevent 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 and may result in less side effects.
- This will also help to prevent the unpleasant taste sensation that some people experience while using these eye drops.
- If necessary, repeat the above steps for the other eye.
- You may feel a slight burning sensation in the eye shortly after using DuoTrav. If it continues, or is uncomfortable, contact your doctor or pharmacist.
- If you want to use any other eye drops wait at least 5 minutes after putting DuoTrav in.

- It is normal for a small amount of eye drops to spill onto your cheek since your eyelids can only hold less than one drop at a time. Wipe away any spillage with a tissue.
- Replace the cap on the bottle and close it tightly.
- Always keep the bottle tightly closed when not in use.
- Wash your hands again with soap and water to remove any residue.
- Discard DuoTrav 4 weeks after opening it.

#### If you forget to use DuoTrav

DuoTrav should be used regularly at the same time each day. If you miss your dose at the usual time, put the drops in as soon as you remember and then go back to using them as told by your doctor.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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

#### If you use too much DuoTrav

If you think that you have used too much DuoTrav, you may need urgent medical attention.

#### You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

# You should do this even if there are no signs of discomfort or poisoning.

If you accidentally put several DuoTrav Eye Drops in your eyes, immediately wash your eyes with warm tap water.

## 5. What should I know while using DuoTrav?

#### Things you should do

- Tell your doctor immediately if you are going to have any surgery.
- Remove soft contact lenses before putting in DuoTrav. Put your lenses back in 15 minutes after putting in the eye drops.

#### Call your doctor straight away if you:

- notice any change in your eye colour.
- have any heart or breathing problems.
- have any changes in your eyelashes such as increased length, thickness, pigmentation, and/or number of lashes or unwanted hollows of the upper eyelid, eyelid skin darkening after starting the treatment with DuoTrav.
- develop any signs of allergic reaction.
- become pregnant, are planning to become pregnant or if you are breast feeding while using DuoTrav.

Remind any doctor, dentist, pharmacist or specialist you visit that you are using DuoTrav.

#### Things you should not do

- Do not stop using this medicine suddenly.
- Do not use DuoTrav in children.
- Do not give DuoTrav to anyone else, even if they seem to have the same condition as you.

#### Driving or using machines

# Be careful before you drive or use any machines or tools until you know how DuoTrav affects you.

DuoTrav may cause temporary blurred vision after putting in the eye drops in some people.

If so, then wait until your vision clears before driving or using machinery.

#### Looking after your medicine

- Store below 25 °C
- Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

#### Keep it where young children cannot reach it.

#### When to discard your medicine

Discard DuoTrav 4 weeks after opening it.

#### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

#### Less serious side effects

• Eyelid swelling

Less serious side effects		What to do
•	Eye irritation	
Ot	her problems:	
•	Dizziness	
•	Severe headache, dizziness, vision problems	
•	Headache	
•	Cough	
•	Tiredness	
•	Unusual hair loss or thinning	
•	Diarrhoea	
•	Feeling sick	
•	Unusual weakness	
•	Stuffy nose	
•	Skin discolouration	
•	Rash	
•	Dizziness, lightheadedness	
•	Headache, feeling sick,	
	weakness, dizziness may	
	indicate low blood sugar level.	

#### Serious side effects

Serious side effects What to do		
Eye problems: Call your		
<ul> <li>Eye problems:</li> <li>Symptoms of allergic reaction may include shortness of breath, difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, hives</li> <li>Swelling of eye with symptoms such as eye pain, decreased vision, blurred vision</li> <li>Inflammation or infection of the thin membrane that covers your eye and the inside of your eyelid.</li> <li>An eye problem that causes blue, brown or grey discoloration around the iris or on the white part of the eye</li> <li>Double vision</li> <li>Inflammation of the cornea, the clear dome-shaped tissue on the front of the eye, symptoms include eye pain, redness, eye sensitivity</li> <li>Droopy eyelid that occurs when the upper eyelid droops over the eye, which can impact your vision.</li> <li>Buildup of fluid in the macula, an area at the back of the eye, with</li> </ul>	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.	
symptoms like blurred vision, distorted vision.		
<ul> <li>Unwanted hollows of the upper eyelid</li> </ul>		

Serious side effects	What to do
<ul> <li>Problems with eyelashes such as eyelash discolouration, increased length, thickness, pigmentation, and/or number of lashes</li> </ul>	
Other problems:	
• fast or irregular heart beat	

#### Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

#### **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at <u>www.tga.gov.au/reporting-problems</u>. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

## 7. Product details

This medicine is only available with a doctor's prescription.

### What DuoTrav contains

Active ingredient (main ingredient)	40 micrograms (0.004%) travoprost and 5 mg (0.5%) timolol (as timolol maleate 6.83 mg)
Other ingredients (inactive ingredients)	Ethoxylated hydrogenated castor oil, propylene glycol, boric acid, mannitol, sodium chloride, sodium hydroxide and/or hydrochloric acid and purified water. The solution is preserved with polyquaternium-1.
Potential allergens	NA

Do not take this medicine if you are allergic to any of these ingredients.

#### What DuoTrav looks like

DuoTrav is a colourless to light yellow aqueous solution. It comes in 2.5 mL bottle with or without a pouch.

#### Australian Registration Number

AUST R: 177772

#### Who distributes DuoTrav

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 1 800 671 203 Web site: <u>www.novartis.com.au</u> \* = Registered Trademark

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