

NOVARTIS SOUTH AFRICA (PTY) LTD  
DUOTRAV eye drops, solution  
Travoprost 40 µg/ml and timolol 5 mg/ml  
PIL Approved: 02 October 2015

## **SCHEDULING STATUS**

S4

## **PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM**

**DUOTRAV Eye drops**, 40 µg/ml, 5 mg/ml, solution

Travoprost, timolol.

## **Read all of this leaflet carefully before you start using DUOTRAV Eye drops**

- Keep this leaflet. You may need to read it again
- If you have further questions, please ask your doctor or your pharmacist.

**DUOTRAV\* Eye drops** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

## **WHAT DUOTRAV® EYE DROPS CONTAINS**

The active substances are travoprost and timolol.

The other ingredients are boric acid, mannitol, polyoxyethylene hydrogenated castor oil, polyquaternium-1 (preservative), propylene glycol, sodium chloride, purified water.

## **WHAT DUOTRAV\* EYE DROPS IS USED FOR**

**DUOTRAV\* Eye Drops** is an eye preparation for reducing the pressure in the eyes.

## **BEFORE YOU USE DUOTRAV\* EYE DROPS**

### **Do not use DUOTRAV\* Eye Drops:**

- if you are hypersensitive (allergic) to travoprost or timolol or any of the other ingredients of **DUOTRAV\*** Eye Drops
- if you have respiratory problems such as asthma, bronchitis or other types of breathing problems
- if you have a slow heartbeat, heart failure or disorders of the heart rhythm.

### **Take special care with DUOTRAV\* Eye Drops:**

- if you have diabetes or low blood sugar
- if you have an over active thyroid
- if you have low blood pressure or circulatory disorders.

## **Pregnancy and Breast-feeding**

You should not use **DUOTRAV\* Eye Drops** during pregnancy or when planning to become pregnant unless adequate contraceptive measures are in place.

You should not use **DUOTRAV\* Eye Drops** if you are breastfeeding your baby.

If you are pregnant or breast feeding your baby please consult your doctor, pharmacist or other health care professional for advice before using **DUOTRAV\*** Eye Drops.

### **Driving and using machinery**

If vision blurs at instillation, wait until the vision has cleared before driving or using machinery.

### **Important information about some of the ingredients of DUOTRAV\* Eye Drops**

Propylene glycol and polyoxyethylene hydrogenated castor oil may cause skin irritation.

### **Using other medicines with DUOTRAV\* Eye Drops**

Always tell your healthcare professional if you are taking any other medicine.

Using **DUOTRAV\* Eye Drops** while taking heart medication such as digoxin may cause low blood pressure.

**DUOTRAV\* Eye Drops** may increase the effect of antidiabetic medicines.

### **HOW TO USE DUOTRAV\* EYE DROPS**

Always use **DUOTRAV\* Eye Drops** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is one drop of **DUOTRAV\* Eye Drops** instilled into the affected eye(s) once daily, either in the morning or in the evening. Use **DUOTRAV\* Eye**

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**Drops** at the same time each day.

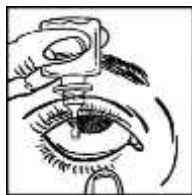
If you are using other eye preparations as well, ensure that the medicines are instilled at least 5 minutes apart.

If you have the impression that the effect of **DUOTRAV\* Eye Drops** is too strong or too weak, talk to your doctor or pharmacist.

***Directions for use***



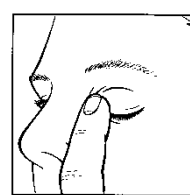
1



2



3



4

- 1 When using a bottle for the first time, tear open the overwrap pouch, take the bottle out (picture 1) and write the date of opening on the label in the space provided.

Wash your hands. Twist off the cap.

- 2 Hold the bottle pointing down between the thumb and first finger.  
Tilt your head back. Pull down on the lower eyelid with your free hand until a 'pocket' forms between the eyelid and the eye. (picture 2).  
Bring the bottle tip close to the eye without touching your eye or eyelid or other surface with the dropper. Use a mirror if necessary.

- 3 Gently squeeze the bottle to release one drop of **DUOTRAV\* Eye Drops** into the eye 'pocket' (picture 3).
- 4 After instilling **DUOTRAV\* Eye Drops** lightly press with a finger into the corner of your eye (picture 4).

If you have been instructed to use the drops in both eyes, repeat steps 1 - 4 for the other eye.

Immediately after use replace the cap on the bottle and close firmly.

Use one bottle at a time. Do not open the pouch of a new bottle until you need to use it.

Do not stop using the drops unless your doctor has instructed you to do so.

**If you use more DUOTRAV\* Eye Drops than you should**

Rinse the eye with warm water and wait until it's time to instil the next dose.

**In the event of overdose, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.**

**If you forget to use DUOTRAV\* Eye Drops**

Continue with the next dose as planned. Do not take a double dose to make up for forgotten individual doses. Do not use more than one drop in the affected eye daily.

## **POSSIBLE SIDE EFFECTS**

**DUOTRAV\* Eye Drops** can have side effects.

### ***Frequent***

Eye pain, eye irritation, foreign body sensation, dry eye, itching, redness.

### ***Less frequent***

Slow heartbeat, low blood pressure, tiredness, light sensitivity, blurred vision, conjunctivitis, eyelid crusting, eyelid itching, eye strain, increased tearing, change in eye colour, growth of eye lashes, dark circles under eyes.

Not all side effects reported for **DUOTRAV\* Eye Drops** are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

## **STORING AND DISPOSING OF DUOTRAV\* EYE DROPS**

**Keep all medicines out of the reach and sight of children.**

Do not store above 25 °C.

Keep the container tightly closed.

Do not use after the expiry date stated on the bottle.

Discard four weeks after first opening.

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Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

### **PRESENTATION OF DUOTRAV\* EYE DROPS**

White 4 ml polypropylene bottle with colourless polypropylene dispensing plug and white polypropylene screw cap.

### **IDENTIFICATION OF DUOTRAV\* EYE DROPS**

Clear, colourless solution.

### **REGISTRATION NUMBER**

A40/15.4/0511

### **NAME AND ADDRESS OF REGISTRATION HOLDER**

Novartis South Africa (Pty) Ltd

Magwa Crescent West

Waterfall City

Jukskei View

2090

### **DATE OF PUBLICATION**

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