NOVARTIS

DUOTRAV® (travoprost/timolol)

travoprost 40 µg/ml and timolol 5 mg/ml, solution

Patient Information Leaflet

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PATIENT INFORMATION LEAFLET

SCHEDULING STATUS **S4**

DUOTRAV® eye drops solution

travoprost/timolol, 40 µg/ml / 5 mg/ml

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 pharmacist, nurse or other health care provider.
- 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 is in this leaflet

1. What DUOTRAV® eye drops is and what it is used for.
2. What you need to know before you use DUOTRAV® eye drops.
3. How to use DUOTRAV® eye drops.
4. Possible side effects.
5. How to store DUOTRAV® eye drops.
6. Contents of the pack and other information.

1 What DUOTRAV® eye drops is and what it is used for

What DUOTRAV® eye drops is:

DUOTRAV® eye drops solution is a combination of two active substances (travoprost and timolol).

DUOTRAV® is a combination of two active substances, travoprost and timolol. Travoprost increases the outflow of the liquid inside the eye, called aqueous humor, and this lowers the pressure. Timolol reduces the production of fluid within the eye. The two substances work together to reduce pressure within the eye.

The two substances work together to reduce pressure within the eye.

What DUOTRAV® eye drops is used for:

DUOTRAV® eye drops is an eye preparation for reducing the pressure in the eyes.

2 What you need to know 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.

Ask your doctor for advice if any of these applies to you.

Warnings and precautions

Take special care with DUOTRAV® eye drops. Tell your doctor:

- if you have diabetes or low blood sugar (as timolol may mask signs and symptoms of low blood sugar);
- if you have an overactive thyroid;
- if you have low blood pressure or circulatory disorders;

- if you have coronary heart disease (symptoms can include chest pain or tightness, breathlessness or choking);
- if you have chronic obstructive pulmonary disease;
- if you get any severe allergic reaction (skin rash, redness, or itching of the eye) while using DUOTRAV®, whatever the cause, the usual treatment for such a reaction (adrenaline/epinephrine) may not be as effective. So when receiving any other treatment please tell your doctor that you are using DUOTRAV®;
- DUOTRAV® may change the colour of your iris (the coloured part of your eye). This change may be permanent. A change in the colour of the skin around the eye may also occur;
- DUOTRAV® may increase the length, thickness, colour and/or number of your eyelashes;
- Tell your doctor if you have eye inflammation or have had it in the past, talk to your doctor before you use DUOTRAV®;
- changes in the eyelid or in the tissues around the eye have been observed with travoprost and similar medicines;
- tell your doctor before surgical anesthesia that you are using DUOTRAV®, as it may change the effects of some medicines used during anesthesia;
- tell your doctor if you have a disease of the surface of your eye (cornea), talk to your doctor, as DUOTRAV® may cause dry eyes.
- DUOTRAV® contains propylene glycol and polyoxyethylene hydrogenated castor oil 40 which may cause skin irritation.
- remove contact lenses prior to application of DUOTRAV® and wait 15 minutes after instillation of DUOTRAV® before reinsertion.

Children/ and adolescents

DUOTRAV® is not to be used by children and adolescents under 18 years of age.

Other medicines and DUOTRAV® eye drops

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following medicines:

- 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;
- oral calcium channel blockers (medicines used to lower blood pressure);
- beta- blocking agents (medicines used for abnormal heart rhythms);
- clonidine (a medicine used to treat high blood pressure);
- quinidine (a medicine used to treat heart conditions and malaria);
- fluoxetine or paroxetine (medicines used to treat depression);
- adrenaline (epinephrine)(a medicine used to treat anaphylactic reactions. Pupil dilation has been reported).

Pregnancy and breastfeeding and fertility

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.

Driving and using machinery

It is not always possible to predict to what extent DUOTRAV® eye drops may interfere with the daily activities of a patient. DUOTRAV® eye drops may cause temporary blurred vision or other visual disturbances and patients should ensure that they do not engage in the above activities e.g. driving or using machinery until they are aware of the measure to which DUOTRAV® eye drops affects them.

DUOTRAV® eye drops contains propylene glycol and polyoxyethylene hydrogenated castor oil

Propylene glycol and polyoxyethylene hydrogenated castor oil may cause skin irritation (*see section 'Warning and Precautions'*).

3 How to use DUOTRAV® eye drops

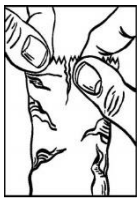
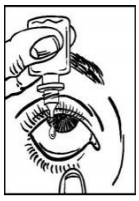
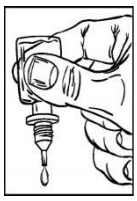
Do not share medicines prescribed for you with any other person.

Always use DUOTRAV® eye drops exactly as your doctor or pharmacist 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 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.
- After using DUOTRAV®, close your eyelids and press a finger into the corner of your eye, by the nose for 2 minutes. This helps to stop DUOTRAV® getting into the rest of the body and increases local activity.

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 overdosage, consult your doctor or pharmacist. If neither is available, contact 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.

4 Possible side effects

DUOTRAV® can have side effects.

Not all side effects reported for DUOTRAV® are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using DUOTRAV®, please consult your healthcare professional for advice.

If any of the following happens, stop using DUOTRAV® eye drops and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- dizziness, fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to DUOTRAV®. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Depression;
- Hallucination (a perception in the absence of reality, seeing, feeling or hearing things that are not there);
- chest pain, palpitations (irregular heartbeat);
- peripheral oedema (accumulation of fluid causing swelling usually in the lower limbs);
- asthma, shortness of breath;

These are all serious side effects. If you have them, you may have had a serious reaction to DUOTRAV® eye drops. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Eye pain, eye irritation, foreign body sensation in eyes, dry eye;
- eye pruritus (itchy eyes);
- conjunctival hyperaemia (reaction that appears as dilation and redness of the conjunctival vessels);
- ocular hyperaemia (redness).

Less frequent side effects:

- nervousness

- photophobia (light sensitivity);
- blurred vision;
- conjunctivitis (pink eye);
- eyelid crusting (itching, burning, mild foreign-body sensation, tearing and crusting around the eyes on awakening);
- asthenopia (eye strain which can cause symptoms such as fatigue, pain in or around the eyes, blurred vision, headache, and occasional double vision);
- increased lacrimation (increased tearing);
- change in eye colour;
- growth of eye lashes;
- dark circles under eyes;
- bradycardia (slow heartbeat);
- hypotension (low blood pressure);
- fatigue (tiredness);
- headache;
- punctate keratitis (eyes become red, watery, and sensitive to light, and vision may decrease somewhat);
- ocular discomfort (when there is lack of ease in/about the eyes);
- abnormal sensation in eye;
- keratoconjunctivitis sicca (dryness of the eye membranes and cornea);
- allergic conjunctivitis (eye inflammation);
- meibomianitis (inflammation of a group oil-releasing glands in the eyelids);
- skin darkening (around the eye).;
- abnormal hair growth;
- decreased heart rate;
- high blood pressure;

- corneal erosion (when the layer of cells on the surface of the cornea, called epithelium, loosens from the layer underneath);
- voice disorders;
- cough;
- throat irritation.

The following side effects have been reported but the frequency is unknown:

- Alopecia (a condition that causes hair to fall out in small patches);
- macular oedema (build-up of fluid in an area in the centre of the retina);
- eyelid ptosis (droopy eyelid);
- lid sulcus deepened (deepening of upper eyelid);
- iris hyperpigmentation
- dysgeusia (a distortion of the sense of taste);

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

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of DUOTRAV®.

5 How to store DUOTRAV® eye drops

- Store all medicines out of reach of children.
- Keep the container tightly closed.
- Store at or below 25 °C.

- Discard four weeks after first opening.
- Store in the original package / container.
- Do not store in a bathroom
- Do not use after the expiry date stated on the bottle .
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6 Contents of the pack and other information

What DUOTRAV® eye drops contains:

- The active substances are: 1 ml of solution contains 40 µg travoprost and 6,83 mg timolol maleate equivalent to 5 mg timolol

- The other ingredients are*:*
  - Boric acid
  - Polyquaternium-1
  - Mannitol (E421)
  - Propylene glycol (E1520)
  - Polyoxyethylene hydrogenated castor oil 40 (HCO-40)
  - Purified water
  - Sodium chloride
  - Sodium hydroxide and/ or hydrochloric acid (for pH adjustment)

What DUOTRAV® eye drops looks like and contents of the pack

What DUOTRAV® eye drops looks like:

Clear colourless solution

Contents of pack:

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

Holder of Certificate of Registration and Manufacturer

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