

Package leaflet: Information for the user

Travoprost Sandoz 40 micrograms/ml Eye drops, solution

travoprost

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Travoprost Sandoz is and what it is used for

Travoprost Sandoz contains travoprost, one of a group of medicines called prostaglandin analogues. It works by reducing the pressure in the eye. It may be used on its own or with other drops e.g. beta-blockers, which also reduce pressure.

Travoprost Sandoz is used to reduce high pressure in the eye in adults, adolescents and children from 2 months old onward. This pressure can lead to an illness called glaucoma.

2. What you need to know before you use Travoprost Sandoz

Do not use Travoprost Sandoz

- if you are allergic to travoprost or any of the other ingredients of this medicine (listed in section 6).

Ask your doctor for advice if this applies to you.

Warnings and precautions

Talk to your doctor or pharmacist before using Travoprost Sandoz.

- Travoprost Sandoz may increase the length, thickness, colour and/or number of your eyelashes. Changes in the eyelids including unusual hair growth or in the tissues around the eye have also been observed.
- Travoprost Sandoz 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.
- If you have had cataract surgery, talk to your doctor before you use Travoprost Sandoz.
- If you have current or previous history of an eye inflammation (iritis and uveitis), talk to your doctor before you use Travoprost Sandoz.
- Travoprost Sandoz may rarely cause breathlessness or wheezing or increase the symptoms of asthma. If you are concerned about changes in your breathing pattern when using Travoprost Sandoz advise your doctor as soon as possible.
- Travoprost may be absorbed through the skin. If any of the medicinal product comes into contact with the skin, it should be washed off straight away. This is especially important in women who are pregnant or are attempting to become pregnant.
- If you wear soft contact lenses, do not use the drops with your lenses in. After using the drops wait 15 minutes putting your lenses back in.

Children and adolescents

Travoprost Sandoz can be used in children from 2 months to < 18 years at the same dose as for adults. Use of Travoprost Sandoz is not recommended to those children under 2 months of age.

Other medicines and Travoprost Sandoz

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.

Pregnancy, breast-feeding and fertility

Do not use Travoprost Sandoz if you are pregnant. If you think that you may be pregnant speak with your doctor right away. If you could become pregnant you must use adequate contraception whilst you use Travoprost Sandoz.

Do not use Travoprost Sandoz if you are breast-feeding. Travoprost Sandoz may get into your milk.

Ask your doctor for advice before taking any medicine.

Driving and using machines

You may find that your vision is blurred for a time just after you use Travoprost Sandoz. Do not drive or use machines until this has worn off.

Travoprost Sandoz contains

- **benzalkonium chloride:** this may cause eye irritation. Avoid contact with soft contact lenses. Remove contact lenses prior to application and wait at least 15 minutes before reinsertion. Benzalkonium chloride is known to discolour soft lenses.

- **macroglycerol hydroxystearate 40:** this may cause skin reactions.

3. How to use Travoprost Sandoz

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor, the doctor treating your child or pharmacist if you are not sure.

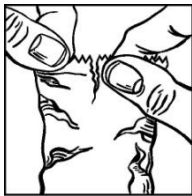
The recommended dose is:

Adults: one drop in the affected eye or eyes, once a day-in the evening.

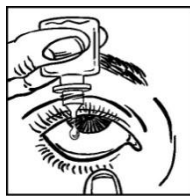
Only use Travoprost Sandoz in both eyes if your doctor told you to. Use it for as long as your doctor told you to.

Only use Travoprost Sandoz for dropping in your or your child's eyes.

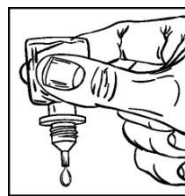
Instruction for use:



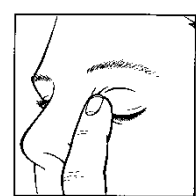
1



2



3



4

- Immediately before using a bottle for the first time, 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.
- Hold the bottle, pointing down, between your thumb and fingers.
- Tilt your head or your child's head gently back. Pull down your eyelid with a clean finger, until there is a 'pocket' between the eyelid and your eye. The drop will go in here (picture 2).
- Bring the bottle tip close to the eye. Use the mirror if it helps.
- Do not touch the eye or eyelid, surrounding areas or other surfaces with the dropper. It could infect the drops.
- Gently squeeze the bottle to release one drop of Travoprost Sandoz at a time (picture 3).
- After using Travoprost Sandoz, keep the eyelid closed, gently press a finger into the corner of the eye, by the nose (picture 4) for at least 1 minute. This helps to stop Travoprost Sandoz getting into the rest of the body.
- If you use drops in both eyes, repeat the steps for the other eye.
- Close the bottle cap firmly immediately after use.
- Only use one bottle at a time. Do not open the pouch until you need to use the bottle.

If a drop misses your eye, try again.

If you or your child are using other eye preparation such as eye drops or eye ointment, wait for at least 5 minutes between putting in Travoprost Sandoz and the other eye preparations.

If you use more Travoprost Sandoz than you should

Rinse all the medicine out with lukewarm water. Don't put in any more drops until it's time for the next regular dose.

If you forget to use Travoprost Sandoz

Continue with the next dose as planned. **Do not use a double dose** to make up for a forgotten dose. Never use more than one drop in the affected eye(s) in a single day.

If you stop using Travoprost Sandoz

Do not stop using Travoprost Sandoz without speaking to your doctor or the doctor treating your child. The pressure in your eye or your child's eye will not be controlled which could lead to loss of sight.

If you have any further questions on the use of this medicine ask your doctor, the doctor treating your child or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects although not everybody gets them.

You can usually carry on using the drops, unless the side effects are serious. If you're worried, talk to a doctor or pharmacist. Do not stop taking Travoprost Sandoz without speaking to your doctor.

The following side effects have been seen with Travoprost Sandoz :

Very common: may affect more than 1 in 10 people

Effects in the eye:

- eye redness

Common: may affect up to 1 in 10 people

Effects in the eye:

- changes in the colour of the iris (coloured part of the eye)
- eye pain
- eye discomfort
- dry eye
- itchy eye
- eye irritation

Uncommon: may affect up to 1 in 100 people

Effects in the eye:

- corneal disorder
- eye inflammation
- iris inflammation
- inflammation inside the eye
- eye surface inflammation with or without surface damage
- sensitivity to light
- eye discharge
- eyelid inflammation

- eyelid redness
- swelling around the eye
- eyelid itching
- reduced vision
- blurred vision
- increased tear production
- infection or inflammation of the conjunctiva (conjunctivitis)
- abnormal turning outward of the lower eyelid
- clouding of the eye
- eyelid crusting
- growth of eyelashes
- discolouration of the eyelashes
- tired eyes

General side effects:

- increased allergic symptoms
- headache
- dizziness
- irregular heart beat
- shortness of breath
- asthma
- stuffy nose
- throat irritation
- darkening of skin around the eye (s)
- changes in the skin colour
- abnormal hair texture
- excessive hair growth

Rare: may affect up to 1 in 1,000 people

Effects in the eye:

- perception of flashing lights
- eczema of the eyelids
- eye swelling
- halo vision
- decreased eye sensation
- inflammation of the glands of the eyelids
- pigmentation inside the eye
- increase in pupil size
- change in the texture of the eyelashes

General side effects:

- eye viral infection
- bad taste
- irregular or decreased heart rate
- increased or decreased blood pressure
- abnormalities when breathing
- pain in the mouth or throat
- cough
- voice changes

- gastrointestinal discomfort or ulcer
- constipation
- dry mouth
- redness or itching of the skin
- rash
- hair colour changes
- loss of eyelashes
- musculoskeletal pain
- generalised weakness

Not known: frequency cannot be estimated from the available data

Effects in the eye:

- inflammation of the back of the eye
- sunken eyes

General side effects:

- depression
- anxiety
- sensation of false movement
- ringing in ears
- chest pain
- heart rate increased
- worsening of asthma
- diarrhoea
- abdominal pain
- nausea
- itching
- abnormal hair growth
- joint pain,
- painful or involuntary urination
- increase in prostate cancer marker

In children and adolescents, the most common side effects seen with Travoprost Sandoz are eye redness and growth of eyelashes. Both side effects were observed with a higher incidence in children and adolescents compared to adults.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine

5. How to store Travoprost Sandoz

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton, the pouch and the bottle label after 'Exp'. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

You must throw away the bottle 4 weeks after you first opened it, to prevent infections, and use a new bottle. Write down the date you opened it in the space on each bottle label and box.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Travoprost Sandoz contains

- The **active substance** is **travoprost**. Each ml of solution contains 40 micrograms travoprost.
- The other ingredients are: Benzalkonium chloride solution, macrogolglycerol hydroxystearate 40, trometamol, disodium edetate, boric acid, mannitol and purified water. Tiny amounts of hydrochloric acid or sodium hydroxide are added to keep acidity levels (pH levels) normal.

What Travoprost Sandoz looks like and contents of the pack

Travoprost Sandoz is a clear, colourless eye drop solution, supplied in a pack containing 1, 3 or 6 plastic dropper container(s) of 2.5 ml, each with a screw cap. Each dropper container is placed in a pouch. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers

Alcon-Couvreur N.V., Rijksweg 14, B-2870 Puurs, Belgium.

Alcon Cusí S.A., Camil Fabra 58, 08320 El Masnou, Barcelona, Spain.

Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia.

Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.

Aeropharm GmbH, Francois-mitterand-allee 1, 07407 Rudolstadt, Germany.

This medicinal product is authorised in the Member States of the EEA under the following names:

Germany	Travoprost – 1 A Pharma 40 Mikrogramm/ml Augentropfen
Austria	Travoprost Sandoz 40 Mikrogramm/ml - Augentropfen
Belgium	Travoprost Sandoz 40 microgram/ml oogdruppels, oplossing
Denmark	Travoprost Sandoz
Finland	Travoprost Sandoz
France	TRAVOPROST SANDOZ 40 microgrammes/ml, collyre en solution
Hungary	Travoprost Sandoz 40 mikrogramm/ml oldatos szemcsepp

Ireland	Travoprost Sandoz 40 micrograms/ml Eye drops, solution
Italy	TRAVOPROST SANDOZ
Luxembourg	Travoprost Sandoz 40 mcg/ml collyre en solution
Malta	Travoprost 40 micrograms/ml eye drops, solution
Netherlands	Travoprost Sandoz 40 microgram/ml, oogdruppels, oplossing
Norway	Travoprost Sandoz
Portugal	Travoprost Sandoz
Spain	Travoprost Sandoz 40 microgramos/ml colirio en solución
Sweden	Travoprost Sandoz
Slovakia	Travoprost Sandoz 40 mikrogramov/ml očná roztoková instilácia
United Kingdom	Travoprost Sandoz 40 micrograms/ml eye drops, solution

This leaflet was last revised in 08.2016