Trusopt® 2% Ophthalmic Solution

(dorzolamide hydrochloride)

Your medicine is available as the above name, but will be referred to as Trusopt throughout this:

Patient Information Leaflet

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

1) What Trusopt is and what it is used for

Trusopt contains dorzolamide which belongs to a group of medicines called "carbonic anhydrase inhibitors".

This medicine is prescribed to lower raised pressure in the eye and to treat glaucoma. This medicine can be used alone or in addition to other medicines which lower the pressure in the eye (so-called beta-blockers).

2) What you need to know before you use Trusopt

Do not use TRUSOPT

- if you are allergic to dorzolamide hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- if you have severe kidney impairment or problems, or a prior history of kidney stones.

Warnings and precautions

Talk to your doctor or pharmacist before using Trusopt.

Tell your doctor or pharmacist about any medical problems you have now or have had in the past, including eye problems and eye surgeries, and about any allergies to any medications.

If you develop any eye irritation or any new eye problems such as redness of the eye or swelling of the eyelids, contact your doctor immediately.

If you suspect that Trusopt is causing an allergic reaction (for example, skin rash, severe skin reaction or itching), stop using this medicine and contact your doctor immediately.

Children

Trusopt has been studied in infants and children less than 6 years of age who have raised pressure in the eye(s) or have been diagnosed with glaucoma. For more information, talk to your doctor.

Elderly

In studies with Trusopt, the effects of this medicine were similar in both elderly and younger patients.

Use in patients with liver impairment

Tell your doctor about any liver problems you now have or have suffered from in the past.

Other medicines and Trusopt

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines (including eye drops). This is particularly important if you are taking another carbonic anhydrase inhibitor such as acetazolamide, or a sulpha drug.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

You should not use this medicine during pregnancy. Tell your doctor if you are pregnant or intend to become pregnant.

Breast-feeding

If treatment with this medicine is required, breast-feeding is not recommended. Tell your doctor if you are breast-feeding or intend to breast-feed.

Driving and using machines

No studies on the effects on the ability to drive or use machines have been performed. There are side effects associated with Trusopt, such as dizziness and blurred vision, which may affect your ability to drive and/or operate machinery. Do not drive or operate machinery until you feel well or your vision is clear.

Trusopt contains benzalkonium chloride

This medicine contains approximately 0.002 mg benzalkonium chloride in each drop which is equivalent to 0.075 mg/ml.

Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards.

Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

3) How to use Trusopt

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The appropriate dosage and duration of treatment will be established by your doctor.

When this medicine is used alone, the recommended dose is one drop in the affected eye(s) in the morning, in the afternoon and in the evening.

If your doctor has recommended you use this medicine with a beta-blocker eye drop to lower eye pressure, then the recommended dose is one drop of Trusopt in the affected eye(s) in the morning and in the evening.

If you are using Trusopt with another eye drop, the drops should be instilled at least 10 minutes apart.

Do not allow the tip of the container to touch the eye or areas around the eye. It may become contaminated with bacteria that can cause eye infections leading to serious damage of the eye, even loss of vision.

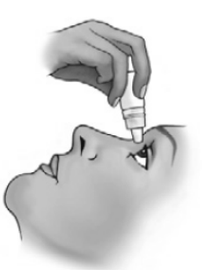
To avoid possible contamination, wash your hands before using this medicine and keep the tip of the container away from contact with any surface. If you think your medication may be contaminated, or if you develop an eye infection, contact your doctor immediately concerning continued use of this container.

Instructions for use

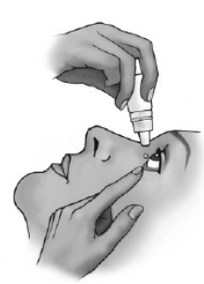
Do not use the container if the plastic safety strip around the neck is missing or broken. When opening the container for the first time, tear off the plastic safety strip.

Every time you use Trusopt:

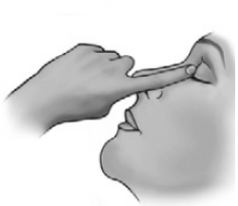
1. Wash your hands.
2. Open the container. **Take special care that the tip of the dropper container does not touch your eye, the skin around your eye or your fingers.**



3. Tilt your head backwards and hold the container upside down over the eye.



4. Pull the lower eyelid downwards and look up. Hold and gently squeeze the container on the flattened sides of the container and let one drop fall into the space between the lower eyelid and the eye.



5. Close your eye and press the inner corner of the eye with your finger for about two minutes. This helps to stop the medicine from getting into the rest of the body.
6. Repeat steps 3 to 5 with the other eye if instructed to do so by your doctor.
7. Put the cap back on and close the container tightly.

If you use more Trusopt than you should

If you put too many drops in your eye or swallow any of the contents of the container, you should contact your doctor immediately.

If you forget to use Trusopt

It is important to take this medicine as prescribed by your doctor. If you miss a dose, take it as soon as possible. However, if it is almost time for the next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for the forgotten dose.

If you stop using Trusopt

If you want to stop using this medicine talk to your doctor first. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4) Possible side effects

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

If you develop allergic reactions including hives, swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing, you should stop using this medicine and seek immediate medical advice.

The following side effects have been reported with TRUSOPT either during clinical trials or during post-marketing experience:

Very common side effects: (affects more than 1 user in 10)
Burning and stinging of the eyes.

Common side effects: (affects 1 to 10 users in 100)
Disease of the cornea with sore eye and blurred vision (superficial punctuate keratitis), discharge with itching of the eyes (conjunctivitis), irritation/inflammation of the eyelid, blurred vision, headache, nausea, bitter taste, and fatigue.

Uncommon side effects: (affects 1 to 10 users in 1,000)
Inflammation of the iris.

Rare side effects: (affects 1 to 10 user in 10,000)
Tingling or numbness of the hands or feet, temporary shortsightedness which may resolve when treatment is stopped, development of fluid under the retina (choroidal detachment, following filtration surgery), eye pain, eyelid crusting, low pressure in the eye, swelling of the cornea (with symptoms of visual disturbances), eye irritation including redness, kidney stones, dizziness, nose bleed, throat irritation, dry mouth, localized skin rash (contact dermatitis), severe skin reactions, allergic type reactions such as rash, hives, itching, in rare cases possible swelling of the lips, eyes and mouth, shortness of breath, and more rarely wheezing.

Not known: (frequency cannot be estimated from the available data)
Shortness of breath, foreign body sensation in eye (feeling that there is something in your eye), forceful heartbeat that may be rapid or irregular (palpitations), increased heart rate and increased blood pressure.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.
You can also report side effects directly via the United Kingdom Yellow Card Scheme: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**.
By reporting side effects you can help provide more information on the safety of this medicine.

5) How to store Trusopt.

- 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 container label and the carton label after 'EXP. The expiry date refers to the last day of that month.
- Trusopt should be used within 28 days after the bottle is opened.
- This medicinal product does not require any special temperature storage conditions.
- Store the bottle in the outer carton in order to protect from light.
- 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.
- If the solution becomes discoloured or shows signs of any deterioration, you should seek the advice of your pharmacist who will tell you what to do.

6) Contents of the pack and other information

What Trusopt contains
The active substance in Trusopt is dorzolamide.

Trusopt contains 2% dorzolamide, a sulphonamide-related compound, as the active ingredient. Each ml contains 22.26mg of dorzolamide hydrochloride equivalent to 20.0mg of dorzolamide.

The other ingredients are hydroxyethylcellulose, mannitol, sodium citrate, sodium hydroxide, and water for injections. Benzalkonium chloride is added as a preservative.

What TRUSOPT looks like and the contents of the pack
TRUSOPT is a clear, colourless, isotonic, buffered, slightly viscous, sterile aqueous solution.

Trusopt is available as plastic dropper bottles containing 5 ml of solution.

PL 46420/0119 **POM**

Who makes and repackages your medicine:
Your medicine is manufactured by Santen Oy, Kelloportinkatu 1, 33100 Tampere, Finland. Procured from within the EU and repackaged by the Product Licence holder: Suerte Pharma Ltd, 4/5 Northolt Trading Estate, Belvue Road, Northolt, Middlesex, UB5 5QS.

Leaflet date: 28.12.2023

How can I learn more about Trusopt, increased eye pressure or glaucoma?
This leaflet gives you the most important information about TRUSOPT. If you have any questions after you have read it, ask your doctor or pharmacist, who can give you more information about TRUSOPT and your eye condition.

Further information about glaucoma is available from:
International Glaucoma Association (IGA)
Woodcote House
15 Highpoint Business Village
Henwood,
Ashford
Kent, TN24 8DH
Tel: 01233 648170
Registered Charity number 274681.

Alternatively, if you or someone you know has problems with their vision, and you require further advice or information, please phone the Royal National Institute for the Blind (RNIB) Helpline on 0303 123 9999.

(The IGA and RNIB are independent UK charities and are not associated with Santen Oy or Suerte Pharma Ltd.)

Santen Oy, Niittyhaankatu 20, 33720 Tampere, Finland.

For any information about this medicine or to request a copy of this leaflet in Braille, large print or audio, please call the PL holder: Suerte Pharma Limited on 020 8839 3000.