

Package leaflet: information for the user

Trusopt® Preservative-Free 20 mg/ml eye drops, solution, single-dose container

(dorzolamide hydrochloride)

XXXXXXX

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 Preservative-Free is and what it is used for
2. What you need to know before you use Trusopt Preservative-Free
3. How to use Trusopt Preservative-Free
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6. Contents of the pack and other information

1. What Trusopt Preservative-Free is and what it is used for

The name of your medicine is Trusopt Preservative-Free 20 mg/ml eye drops, solution, single-dose container but will be referred to as Trusopt Preservative-Free throughout this leaflet. Trusopt Preservative-Free 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 Preservative-Free

Do not use Trusopt Preservative-Free

- 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.

If you are not sure whether you should use this medicine, contact your doctor or pharmacist.

Warnings and precautions

Talk to your doctor or pharmacist before using Trusopt Preservative-Free.

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 Preservative-Free is causing an allergic reaction (for example, skin rash, severe skin reaction, or itching), stop using this medicine and contact your doctor immediately.

If you wear contact lenses, you should consult your doctor before using Trusopt Preservative-Free.

Use in children

Trusopt (preserved formulation) 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.

Use in elderly

In studies with Trusopt (preserved formulation), 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 Preservative-Free

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 any medicine.

Pregnancy

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

Breast-feeding

You should not use this medicine during breast-feeding. 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 Preservative-Free, 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.

3. How to use Trusopt Preservative-Free

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 Preservative-Free in the affected eye(s) in the morning and in the evening.

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

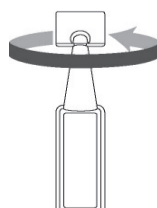
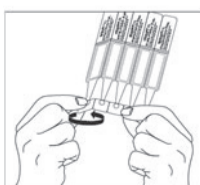
Do not change the dose of the drug without consulting your doctor.

Do not allow the tip of the single dose 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 of the single dose container, wash your hands before using this medicine and keep the tip of the single dose container away from contact with any surface.

Instructions for use:

The solution from one individual single dose container of Trusopt Preservative-Free is to be used immediately after opening for administration to the affected eye(s). Since sterility cannot be maintained after the individual single dose container is opened, a new container must be opened prior to each use and must be discarded immediately after administration. Each single dose container contains enough solution for both eyes.

1. Open the foil sachet which contains the individual single dose containers.
2. First wash your hands then break off one single dose container from the strip and twist open the top of the single dose container as shown.



3. Tilt your head back and pull your lower eyelid down slightly to form a pocket between your eyelid and eye as shown.



- Put one drop in the affected eye(s) as directed by your doctor.
- After putting the drop into the eye, throw away the used single dose container even if there is solution remaining to avoid contamination of the preservative free solution.
- Store the remaining containers in the foil sachet; the remaining containers must be used within 15 days after opening of the sachet. If there are any containers left 15 days after opening the sachet they should be safely thrown away and a fresh sachet opened. It is important to continue to use the eye drops as prescribed by your doctor.

If you use more Trusopt Preservative-Free 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 Preservative-Free

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 Preservative-Free

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 punctate 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 users 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: (cannot be estimated from the available data)

Shortness of breath, foreign body sensation in eye (feeling that there is something in your eye).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed on this leaflet. You can also report side effects directly via the Yellow Card Scheme at: 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 Preservative-Free

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

Do not use the unopened sachets of this medicine after the expiry date which is stated by the six digits following EX (or EXP) on the outer carton, foil package and each single-dose container. The first two digits indicate the month; the last four digits indicate the year. The expiry date refers to the last day of that month.

Do not store above 30°C. Do not freeze.

Store in the foil sachet in order to protect from light.

You can use Trusopt Preservative-Free 15 days after first opening the sachet.

Discard any unused single dose containers after that time.

Discard the opened single dose container with any remaining solution immediately after first use.

If this medicine becomes discoloured or shows any other signs of deterioration, please contact your pharmacist who will advise you on what to do.

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 Trusopt Preservative-Free contains

- The active substance is dorzolamide.
- Each 1ml contains 20 mg of dorzolamide (as dorzolamide hydrochloride).
- The other ingredients are hydroxyethyl cellulose, mannitol, sodium citrate, sodium hydroxide for pH adjustment, and water for injections.

What Trusopt Preservative-Free looks like and contents of the pack

Trusopt Preservative-Free is a clear, colourless to nearly colourless slightly viscous solution. Low density polyethylene single dose containers containing 0.2 ml of solution are sealed in aluminum sachets.

Pack size:

60 x 0.2 ml (4 sachets with 15 single-dose containers)

Product Licence Holder and Manufacturer

Procured from within the EU by the Product Licence holder Orifarm A/S, Energvej 15, 5260 Odense S, Denmark

Repacked by Orifarm Supply s.r.o., Palouky 1366, 253 01 Hostivice, Czech Republic

Manufactured by

Laboratoires Merck Sharp & Dohme Chibret

(MIRABEL PLANT)

Route de Marsat, RIOM

63963 Clermont-Ferrand, Cedex 9, France

**Trusopt Preservative-Free 20 mg/ml eye drops, solution, single-dose container
PL 46927/0082**

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