Patient Leaflet According to the Pharmacists' Regulations (Preparations) – 1986

This medicine is sold with a doctor's prescription only

TRUSOPT

Eye drops

Active ingredient:

Dorzolamide (as hydrochloride) 20 mg/ml

For the list of additional ingredients, see section 6. See also 'Important information about some of the medicine's ingredients' in section 2.

Read this entire leaflet carefully before using the medicine.

This leaflet contains concise information about the medicine. If you have any further questions, please refer to your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. What is the medicine intended for?

The medicine is intended for lowering raised pressure in the eye and for treating glaucoma.

Therapeutic Group: carbonic anhydrase inhibitors.

2. Before using the medicine

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the additional ingredients the medicine contains (for a list of the other ingredients, see section 6).
- If you have severe kidney impairment or problems, or a prior history of kidney stones.

Special warnings regarding the use of this medicine:

Before (and during) treatment with the medicine, tell your doctor if:

- You suffer or have suffered in the past from any medical problems, including eye problems and/or eye surgeries.
- You suffer from any allergy to medicines.
- You suffer or have suffered in the past from liver problems.
- You suffer or have suffered in the past from impaired kidney function - see also the "Do not use the medicine if" section.

Additional warnings

- If you are sensitive to any type of food or medicine, including sulfonamide-derived drugs, inform your doctor before using this medicine.
- If while using the medicine 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 the medicine 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 think that the medicine has become contaminated, or if you develop an eye infection, contact your doctor immediately about continuing use of the bottle. See also section 3.

Children and adolescents: there is no information on the safety and effectiveness of use of this medicine in children and adolescents.

Drug interactions:

If you are taking, or have recently taken any other medicines, including non-prescription medicines and nutritional supplements, please tell your doctor or pharmacist. Especially inform your doctor or pharmacist if you are taking the following medicines (it should be noted that the following list indicates the active ingredients in the medicines. If you are not sure whether you are using one of these medicines please check with your doctor or pharmacist):

- Other eye drops.
- Other medicines from the carbonic anhydrase inhibitor class such as acetazolamide.

- Medicines containing sulfa.

Pregnancy and breastfeeding:
If you are pregnant, think you are pregnant, are planning a pregnancy or if you are breastfeeding, consult your doctor before taking the medicine.

- **Pregnancy**: do not use this medicine during pregnancy. Tell your doctor if you are pregnant or plan to become pregnant. There is insufficient information on the use of this medicine during pregnancy.
- **Breastfeeding**: It is not known whether the medicine passes into the breastmilk. If treatment with this medicine is required, breastfeeding is not recommended. Tell your doctor if you are breastfeeding or if you are planning to breastfeed.

Driving and use of machinery:
There are side effects associated with use of the medicine, 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 and/or your vision is clear.

Important information about some of the medicine's ingredients:

This medicine contains approximately 0.075 mg/ml benzalkonium chloride (preservative). Benzalkonium chloride may be deposited in soft contact lenses and may change the color of the contact lenses. If you use contact lenses, remove them before using this medicine and wait at least 15 minutes before putting them back.
Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea. If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

3. How to use this medicine?

Always use the medicine according to the doctor's instructions. Check with your doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.
The dosage and the manner and length of treatment will be determined by the doctor only.
This medicine is indicated for use in the eyes. Do not swallow!

The standard dosage is usually: one drop in the affected eye(s) 3 times daily.
If you use TRUSOPT with other eye drops or with another preparation for topical treatment of the eye, they must be used at least 10 minutes apart.
Do not exceed the recommended dosage.
Use this medicine at set times as determined by your attending doctor.
Do not allow the tip of the bottle to come into direct contact with your fingers, eyes or with the areas around the eyes, to prevent infection (which may lead to serious damage of the eye and even loss of vision).
You must also wash your hands before using the medicine and prevent the tip of the bottle from coming into contact with any surface. Close the bottle tightly.
If you think that the medicine has become contaminated, or if you develop an eye infection, talk to your doctor immediately about continuing use of the bottle.

Manner of use

1. Before use wash your hands thoroughly.

Opening arrows

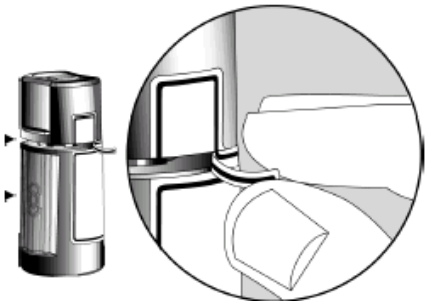
Safety strip

2. Before using the preparation for the first time, check that the safety strip on the front of the bottle is unbroken. A gap between the bottle and the cap is normal for an unopened bottle.

3. Tear off the safety strip (seal) to break the seal.

Gap

Finger Push Area

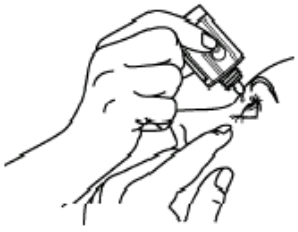


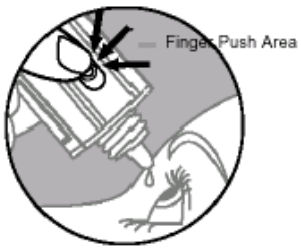
4. To open the bottle, unscrew the cap by turning as indicated by the arrows.

Finger Push Area

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

6. Invert the bottle and press lightly with the thumb or index finger over the “Finger Push Area” (as shown) until a single drop is dispensed into the eye as directed by your doctor. **Do not touch your eye or eyelid with the tip of the bottle**





7. Repeat steps 5 & 6 with the other eye if instructed to do so by your doctor.
8. Replace the cap by turning until it is firmly touching the bottle. Do not overtighten the cap.
9. The dispenser tip is designed to provide a pre-measured drop; therefore, do **not** enlarge the hole of the dispenser tip.
10. After you have used all the doses, there may be some solution left in the bottle. You should not be concerned since an extra amount of solution has been added and you will get the full amount of TRUSOPT that your doctor prescribed. Do not attempt to remove the excess amount of the solution from the bottle.
11. Do not use this medicine for more than 1 month after the bottle is first opened.

If you have accidentally taken a higher dosage: if you put too many drops in your eye or if somebody has accidentally swallowed the medicine, proceed immediately to the doctor and bring the medicine package with you.
Overdose symptoms can include drowsiness (if the drops are swallowed), nausea, dizziness, headache, fatigue, unusual dreams, impaired swallowing.

If you forgot to take the medicine: it is important to take the medicine as prescribed by the doctor. If you forgot to instill a dose at the set time, instill it as soon as possible, but if it is almost time for the next dose, skip the forgotten dose, and continue use according to the regular schedule. Do not use a double dose to compensate for the forgotten dose.

Adhere to the treatment as recommended by your doctor. Even if your state of health improves, do not stop the treatment with this medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and the dose <u>each time</u> you take a medicine. Wear glasses if you need them.
If you have further questions concerning the use of the medicine, consult your doctor or pharmacist.

4. **Side effects**

As for any medicine, the use of TRUSOPT may cause side effects in some users. Do not be alarmed while reading the list of side effects. You may not suffer from any of them.
Stop treatment and seek immediate medical assistance if the following side effects appear:

- If you develop an allergic reaction including hives (urticaria), swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing.

<u>Additional side effects (including frequency):</u>

Very common side effects (appear in more than 1 user out of 10):
Burning and stinging of the eyes.
Common side effects (appear in 1-10 users out of 100):
Disease of the cornea with sore eye and blurred vision (superficial punctuate keratitis), discharge with itching of the eyes (conjunctivitis), tearing, irritation/inflammation of the eyelids, itching in the eye, blurred vision, headache, nausea, bitter taste, fatigue/weakness.
Uncommon side effects (appear in 1-10 users out of 1,000):
Inflammation of the iris.
Rare side effects (appear in 1-10 users out of 10,000):
Tingling or numbness, temporary shortsightedness which may resolve when treatment is stopped, accumulation of fluid under the retina (choroidal detachment, following filtration surgery), eye pain, eyelid crusting, low pressure in the eye, edema (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 (Stevens-Johnson syndrome, toxic epidermal necrolysis), allergic type reactions such as rash, hives (urticaria), itching, in rare cases possible swelling of the lips, eyes and mouth, shortness of breath, wheezing.
Side effects of unknown frequency (effects whose frequency has not yet been determined):

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).

If a side effect appears, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with your doctor.
Side effects may be reported to the Ministry of Health by clicking on the link "Report on side effects following medicinal treatment" on the homepage of the Ministry of Health website (www.health.gov.il) which leads to an online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il/

5. How to store the medicine?

- Avoid poisoning! This medicine, and any other medicine, must be stored in a closed place out of the reach and sight of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.
- Storage conditions: store below 30°C. Protect from light.
  Do not use this medicine for more than 1 month after the bottle is first opened and no later than the expiry date indicated on the package.

6. Additional information

In addition to the active ingredient, the medicine also contains:
Mannitol, Hydroxyethylcellulose, Sodium citrate, Benzalkonium chloride, Sodium hydroxide, Water for injection.

What does the medicine look like and what does the package contain?
Clear, colorless or nearly colorless, slightly viscous solution in plastic 5 mL bottle.
Manufacturer: Fareva Mirabel, Clermont-Ferrand, France
Registration holder: Rafa Laboratories Ltd., P.O. Box 405, Jerusalem 9100301
Medicine registration number in the National Medicines Registry of the Ministry of Health:
106-58-28935

Revised in March 2021 in accordance with the Ministry of Health directives.

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