Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Dorzolamide S.K.

Eye drops

Active ingredient:

Each ml contains:

Each 1 ml contains: 20 mg dorzolamide (hydrochloride) (2%)

Inactive ingredients and allergens: section 2 under "Important information about some of this medicine's ingredients", and section 6 "Additional information".

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. 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 this medicine intended for?

The medicine is intended for reduction of high intraocular pressure and treatment of glaucoma.

Therapeutic group:

carbonic anhydrase inhibitors

2. Before using this medicine

Do not use this medicine if:

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

Special warnings about using this medicine

Before using Dorzolamide S.K., 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

Special warnings while using the medicine:

- If you are sensitive to any type of food or medicine, including sulfonamide-derived drugs, inform your doctor before using this medicine.
- If during treatment with this medicine eye irritation or any other new eye problem occurs, such as redness or swelling of the eyelids, contact your doctor immediately!
- If you feel that the product is causing an allergic reaction (for example, skin rash or itching), stop its use and contact your doctor promptly.
- 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 other medicines, including nonprescription medications and dietary supplements, 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):

- Treatment with another eye drops
  - Other medicines from the carbonic anhydrase inhibitor class such as acetazolamide.
  - Medicines containing sulfa.
  -

Pregnancy, breastfeeding, and fertility:

If you are pregnant, think you might be pregnant, plan to become pregnant or if you are breastfeeding, consult your doctor or pharmacist before using this 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 using machines:

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 this medicine's ingredients

This medicine contains benzalkonium chloride as a preservative, which may be deposited in soft contact lenses. Therefore, remove the lenses before instilling the drops and wait for at least 15 minutes before reinserting them.

Benzalkonium chloride may cause eye irritation, especially if you suffer from dry eyes or disorders of the cornea (the clear layer in front of the eye). If you have an unusual sensation in the eyes, tingling or pain in the eye after using the drops, contact the doctor.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions.

Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine.

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 are using another topical ophthalmic medication or if you have to use an additional topical ophthalmic medication, ensure an interval of at least 10 minutes between the use of the medication and instillation of Dorzolamide S.K.

Do not exceed the recommended dose.

Mode of administration:

This medicine is to be used at specific time intervals as determined by the 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.

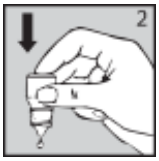
If you think that the medicine has become contaminated, or if you develop an eye infection, talk to your doctor immediately about continuing use of the bottle.

Instructions for use:

1. To avoid contamination, do not let the tip of the bottle touch any surface (including the eye itself). Keep the bottle tightly closed.

2. The drop bottle may not be full; this is intended to allow better control of the dripping rate.

3. How to use the drops: First wash your hands. Tilt your head backwards. Using the index finger, pull the lower eyelid down to form a sort of "pocket". Instill the medicine into the "pocket" formed. Close your eyes gently. Do not blink. Keep the eyes closed for 1 to 2 minutes.



4. In addition to the instructions provided above – immediately after instilling the drops into the eye, press with the middle finger on the inner corner of the eye. Continue pressing for 1 to 2 minutes after instillation into the eye. This action prevents avoiding medicine absorption into the body, thus helping to prevent side effects.

5. Repeat the above steps in the other eye if instructed to treat both eyes by your doctor.

6. Immediately after using the medicine, close the cover tightly and wash your hands thoroughly to clean them from residual medicine.

7. To avoid transmission of infection, the medicine container should not be used for more than one person.

8. Do not use this medicine for more than 28 days after the bottle is first opened and no later than the expiry date indicated on the package.

If you have taken an overdose, if you put too many drops in your eye or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room 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 forget 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 health improves, do not stop taking this medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and dose <u>every time</u> you take a medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. <u>Side effects</u>

Like with all medicines, using Dorzolamide S.K. may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience 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 you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link:
https://sideeffects.health.gov.il

5. How to store the medicine?

Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use the medicine after the expiry date (exp. date) which is stated on the carton package and label. The expiry date refers to the last day of that month.

Storage conditions:

Store at a temperature below 25˚C. Protect from light. Store in the original package.

The medicine can be used for 28 days after first opening, and no later than the expiry date of the medicine.

6. Additional information

In addition to the active ingredient, this medicine also contains:

Mannitol, hydroxyethylcellulose, sodium citrate dihydrate, benzalkonium chloride, sodium hydroxide 1N, water for injection.

What the medicine looks like and contents of the pack:

Dorzolamide S.K. is almost colorless, slightly viscous solution in a vial containing 5 ml with a dispenser tip.

One vial per pack.

Registration holder's name and address:

K.S. Kim International Ltd., 94 Yigal Alon St., Tel-Aviv-Yaffo, 6789139.

Manufacturer's name and address:

RAFARM S.A.,

12 KORINTHOU ST.,154 51 N PSIHIKO ATHENS, GREECE

Revised in August 2022.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
164-10-35562

KS_DORZ_PIL_03_2020_v06