NOVARTIS

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

Azopt 1%

Eye drops (suspension)

Active ingredient:
Each 1 ml contains: brinzolamide 10 mg

The inactive ingredients are listed in section 6 - "Further Information".
Also see "Important information about some of the ingredients of the medicine" in Section 2.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the 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.
This medicine is not intended for use in infants, children and adolescents under the age of 18, since there are no data about the safety and efficacy of the preparation in this population.

1. WHAT IS THE MEDICINE INTENDED FOR?

Azopt 1% eye drops are used to decrease intraocular pressure in patients with ocular hypertension or in open-angle glaucoma patients, in patients who are unresponsive to beta-blockers, who cannot take beta-blockers or as adjunctive therapy to beta-blockers.
Therapeutic group: Carbonic anhydrase inhibitors – intraocular pressure-reducing medicines.
Intraocular pressure that is too high can damage your vision.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:
- You are sensitive (allergic) to brinzolamide or to any of the other ingredients contained in the medicine (see Section 6).
- You have severe kidney problems.
- You have an allergy to sulfonamides. This family of medicines includes, for example, medicines to treat diabetes, infectious diseases and diuretics. Azopt 1% can cause the same allergy.
- You have increased blood acidity (hyperchloraemic acidosis).

If you have further questions, consult the doctor.

Special warnings regarding use of the medicine
Before treatment with Azopt 1%, tell the doctor if:
- You suffer from liver or kidney problems.
- You suffer from dryness of the eyes or cornea problems.
- You are taking other sulfonamides.
- You have a certain form of glaucoma in which the pressure inside the eye rises due to deposits that block fluid drainage (pseudoexfoliative glaucoma or pigmentary glaucoma) or a certain form of glaucoma in which the pressure in the eye increases (sometimes rapidly) due to the eye protruding forward and blocking fluid drainage (narrow-angle glaucoma).
- You have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after using Azopt 1% or other related medicines.

Special caution is required when using Azopt 1% in the following situations:
Serious skin reactions including Stevens-Johnson syndrome and toxic epidermal necrolysis have been reported in association with brinzolamide treatment. Stop using Azopt 1% and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Drug interactions:
If you are taking, have recently taken or intend to take, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular, if you are taking or plan to take:
- Other medicines from the carbonic anhydrase inhibitor group (e.g., acetazolamide or dorzolamide).

Pregnancy and breastfeeding:
If you are pregnant, are planning a pregnancy, think you may be pregnant or are breastfeeding, consult a doctor or pharmacist before using the medicine.
Women who may become pregnant should use effective contraceptives during the course of treatment with Azopt 1%.
Use of Azopt 1% is not recommended for pregnant or breastfeeding women.
Do not use Azopt 1%, unless instructed by the doctor.

Consult your doctor or pharmacist before taking any medicine.

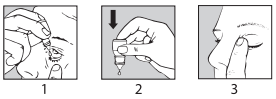
Driving and use of machinery:
Do not drive or operate machines until your vision is clear. You may notice that your vision is blurry for a while after using Azopt 1%.
Use of Azopt 1% may impair the ability to perform activities that require mental alertness and/or physical coordination. If you are affected, exercise caution when driving or using machines.

Important information about some of the ingredients of the medicine:
The medicine contains 3.35 mcg benzalkonium chloride per drop (= 1 dose) equivalent to 0.01% or 0.1 mg/ml.
This preparation contains a preservative (benzalkonium chloride) which may be absorbed by soft contact lenses and discolor them. Remove the lenses before using the preparation; they can be put back into the eyes after 15 minutes have passed.
Benzalkonium chloride may also cause eye irritation, especially if you suffer from dry eyes or disturbances of the cornea (the clear layer at the front of the eye). If you have an unusual sensation in the eyes, stinging or pain in the eye after using the drops, refer to your doctor.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.
The dosage and treatment regimen will be determined by the doctor only. The usual dosage is generally one drop, two or three times a day, in each treated eye.
Treat both eyes only if the doctor has instructed to do so.

Do not exceed the recommended dose.
This medicine is intended for use in the eyes only. Do not swallow or inject.
Shake the bottle well before use.
Instructions for using the medicine:
To avoid contamination, do not allow the tip of the bottle to touch any surface (including the eye itself). Keep the bottle closed tightly.
The bottle of drops may not be full; this is to allow better control of the drip rate.
How to use the drops:



First, wash your hands. Tilt your head back. With your index finger, pull the lower eyelid down, to create a type of "pocket" (Figure 1). Instill the medicine into the "pocket" that has been formed. Close your eyes gently. Do not blink. Keep your eyes closed for 1 to 2 minutes.
Do not squeeze the bottle; pressing gently on the base of the bottle is enough to release the drop (Figure 2).
In addition to the instructions provided above – immediately after instilling the drops into the eye, press the inner corner of the eye with your middle finger. Continue applying pressure for 1 to 2 minutes after instilling into the eye. This action helps prevent the medicine from being absorbed into the body, thus helping to prevent side effects (Figure 3).
Repeat the above actions in the other eye, if the doctor has instructed to treat both eyes.
Immediately after using the medicine, close the cap tightly and wash your hands thoroughly to clean them from remnants of medicine.
To avoid spreading infection, do not use the same bottle of medicine for more than one person.
If a drop missed the eye, try again.
If you accidentally took a higher dosage, wash the eye with warm water. Do not apply another dose until the time for the next dose.
If you took an overdose, or if a child accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.
If you forgot to take a medicine at the required time, instill one drop as soon as you remember, and continue with the regular regimen. Do not take a double dose to compensate for the forgotten dose.
If you are using other eye drops, wait at least 5 minutes between administration of this medicine and administration of the other eye drops. Use eye ointments last.
Adhere to the treatment regimen as recommended by the doctor. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.
If you stop taking the medicine without consulting the doctor, the intraocular pressure will not be controlled, which may cause loss of vision.
Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.
If you have further questions regarding use of the medicine, consult with the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Azopt 1% may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.
Stop using Azopt 1% and seek medical attention immediately if you notice any of the following symptoms:
reddish non-elevated, target-like or circular patches on the trunk (back, chest, abdomen, pelvis), often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis).
Common side effects - effects that occur in 1-10 in 100 users:
Eye effects:
Blurred vision, eye irritation, pain in the eye, discharge from the eye, itching in the eye, dry eyes, unusual sensation in the eye, redness in the eye.
General side effects:
Bad taste.
Uncommon side effects - effects that occur in 1-10 in 1,000 users:
Eye effects:
Sensitivity to light, conjunctiva inflammation or infection, eye swelling, itching in the eyelids, redness or swelling, deposits in eye, glare, burning sensation, growth on the surface of the eye, increased eye pigmentation, eye fatigue, formation of crust on the eyelid or excessive tear production.
General side effects:
Reduced heart function, strong palpitations that may be rapid or irregular, slower heart rate, difficulty breathing, breathlessness, cough, reduced number of red blood cells in blood counts, increased chloride level in the blood, dizziness, difficulty in memory, depression, nervousness, reduced emotional interest (apathy), nightmares, generalized weakness, fatigue, an unusual feeling, pain, movement problems, reduced libido, male sexual difficulty, cold symptoms, chest congestion, sinusitis, throat irritation, sore throat, reduced or abnormal sensation in the mouth, esophagitis, abdominal pain, nausea, vomiting, indigestion, frequent bowel movements, diarrhea, flatulence, digestive disturbances, kidney pain, muscle pain, muscle cramps, back pain, nosebleeds, runny nose, nasal congestion, sneezing, rash, abnormal skin sensation, itching, smooth skin rash or redness covered by elevated bumps, taut skin, headaches, dryness in mouth, particles in the eye.
Rare side effects - effects that occur in 1-10 in 10,000 users:
Eye effects:
Corneal swelling, reduced vision or double vision, vision impairment, light flashes in the field of vision, reduced eye sensitivity, swelling around the eye, increased intraocular pressure, damage to the optic nerve.
General side effects:
Memory impairment, drowsiness, chest pains, upper respiratory tract congestion, sinus congestion, nasal congestion, nasal dryness, tinnitus, hair loss, general itching, nervousness, irritation, irregular heart rate, weakness in the body, difficulty falling asleep, wheezing, itchy skin rash.
Side effects of unknown frequency (effects whose frequency has not yet been determined):
Eye effects:
Eyelid disturbances, vision disturbances, corneal disturbance, eye allergy, reduced number or growth of eyelashes, eyelid redness.
General side effects:
Increased allergic symptoms, reduced sensation, tremor, loss or reduced sense of taste, drop in blood pressure, elevated blood pressure, increased heart rate, joint pain, asthma, pain in limbs, skin redness, inflammation or itching, abnormal liver function test results, swelling of limbs, frequent urination, reduced appetite, general unwell feeling, reddish non-elevated, target-like or circular patches on the trunk (back, chest, abdomen, pelvis), often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes, which can be preceded by fever and flu-like symptoms. These serious skin reactions can be potentially life-threatening (Stevens-Johnson syndrome, toxic epidermal necrolysis).
If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Reporting side effects
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine should be kept in a safe place out of the reach and sight of children and/or infants in order 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) that appears on the carton/label. The expiry date refers to the last day of that month.
- Store at a temperature between 4°C and 30°C.
- The bottle should be thrown away one month after first opening in order to avoid contamination. Write the opening date on the bottle.
- After completing treatment, do not discard this medicine in the waste bin. Consult the pharmacist about how to discard medicines that are no longer in use. This will help protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:
Mannitol, Carbomer (974P), Sodium chloride, Tyloxapol, Benzalkonium chloride, Disodium edetate, Sodium hydroxide, Hydrochloric acid, Purified water.
What the medicine looks like and the contents of the package:
Azopt 1% is a milky fluid (suspension) in a plastic bottle which contains 5 ml of eye drops.
Registration Holder and Importer and its address: Novartis Israel Ltd., P.O.B 7126, Tel Aviv.
Revised in July 2022 according to MOH guidelines.
Registration number of the medicine in the National Drug Registry of the Ministry of Health: 136 60 29640

AZO APL JUL 22 V5