

AZARGA® Eye Drops

Brinzolamide/ Timolol (10mg/ml, 5mg/ml)

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What AZARGA is used for

Azarga is used to treat high pressure in the eyes, also called glaucoma or ocular hypertension, in adult patients and in whom high pressure in the eyes cannot be controlled effectively by one medicine alone.

How AZARGA works

Azarga contains two active substances: brinzolamide and timolol which work together to reduce pressure within the eye.

Before you use AZARGA

When you must not use it

Do not use Azarga:

- If you are allergic to brinzolamide, timolol, or any of the other ingredients of this medicine.
- If you are allergic to medicines called sulphonamides. Examples include medicines used to treat diabetes, infections and also diuretics (water tablets). Azarga may cause allergic reaction.
- If you have now or have had in the past respiratory problems such as asthma, severe long lasting obstructive bronchitis (severe lung condition which may cause wheezing, difficulty in breathing and/or long standing cough) or other types of breathing problems.
- If you have severe hay fever.
- If you have a slow heart beat, heart failure or disorders of heart rhythm (irregular heartbeats).

- If you have too much acidity in your blood (a condition called hyperchloraemic acidosis).
- If you have severe kidney problems.

Pregnancy and breast-feeding

You should not use Azarga if you are pregnant or might get pregnant, unless your doctor considers it necessary. Talk to your doctor before you use Azarga.

Do not use Azarga if you are breast-feeding. Timolol may get into your milk.

Ask your doctor for advice before taking any medicine during breastfeeding.

Before you start to use it

Azarga contains a preservative (benzalkonium chloride) which 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.

Talk to your doctor or pharmacist before using Azarga if you have or have had in the past:

- coronary heart disease (symptoms can include chest pain or tightness, breathlessness or choking), heart failure, low blood pressure
- disturbances of heart rate such as slow heart beat
- breathing problems, asthma or chronic obstructive pulmonary disease
- poor blood circulation disease (such as Raynaud's disease or Raynaud's syndrome)

- diabetes as timolol may mask signs and symptoms of low blood sugar
- overactivity of the thyroid gland as timolol may mask signs and symptoms of thyroid disease
- muscular weakness (myasthenia gravis)
- tell your doctor before you have an operation that you are using Azarga as timolol may change effects of some medicines used during anaesthesia.
- if you have a history of atopy (a tendency to develop an allergic reaction) and severe allergic you may be more sensitive to developing an allergic reaction whilst using Azarga and adrenaline may not be as effective to treat an allergic reaction. When receiving any other treatment please tell the doctor or nurse that you are taking Azarga.
- if you have liver problems.
- if you have dry eyes or cornea problems.
- if you have problems with your kidneys.
- if you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after using Azarga or other related medicines.

Take special care with Azarga:

Serious skin reactions including Stevens-Johnson syndrome and toxic epidermal necrolysis have been reported in association with brinzolamide treatment. Stop using Azarga and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 'Side Effects'.

Taking other medicines

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Azarga can affect or be affected by

AZARGA[®] Eye Drops

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other medicines you are using, including other eye drops for the treatment of glaucoma. Tell your doctor if you are using or intent to take medicines to lower blood pressure like parasympathomimetics and guanetidine, or other heart medicines including quinidine (used to treat heart conditions and some types of malaria), amiodarone or other medicines to treat heart rhythm disorders and glycosides to treat heart insufficiency. Also tell your doctor if you are taking or intend to take medicines to treat diabetes, or to treat gastric ulcers, antifungal, antiviral or antibiotic medicines, or antidepressants such as fluoxetine and paroxetine.

If you are taking another carbonic anhydrase inhibitor (acetazolamide or dorzolamide), talk to your doctor.

Increase in pupil size when taking Azarga and adrenaline (epinephrine) together has been reported occasionally.

How to use AZARGA



1



2



3

- Get the Azarga bottle and a mirror.
- Wash your hands.
- Shake well before use.
- Twist off the bottle cap. After the cap is removed, if the tamper evident snap collar is loose, remove before using product.
- Hold the bottle, pointing down, between your thumb and fingers.
- Tilt your head back. Pull down your eyelid with a clean finger, until there is a 'pocket' between the eyelid and your eye. The drop will go in here (picture 1).
- Bring the bottle tip close to the eye. Use the mirror if it helps.
- Do not touch your eye or eyelid, surrounding areas or other

surfaces with the dropper. It could infect the drops.

- Gently press on the base of the bottle to release one drop of Azarga at a time.
- Do not squeeze the bottle: it is designed so that a gentle press on the bottom is all that it needs (picture 2).
- After using Azarga, press a finger into the corner of your eye, by the nose for 2 minutes (picture 3). This helps to stop Azarga getting into the rest of the body.
- If you use drops in both eyes, repeat the steps for your other eye.
- Close the bottle cap firmly immediately after use.
- Use up one bottle before opening the next bottle.

How much to use

One drop in the affected eye or eyes, twice a day.

Only use Azarga in both eyes if your doctor told you to.

When to use it

Use as directed by your doctor or pharmacist.

How long to use it

Take it for as long as your doctor told you to.

If you stop using Azarga without speaking to your doctor, the pressure in your eye will not be controlled which could lead to loss of sight.

If you forget to use it

If you forget to use Azarga, continue with the next dose as planned. Do not use double dose to make up for the forgotten dose. Do not use more than one drop in the affected eye(s) twice daily.

If you use too much (overdose)

If you use more Azarga than you should, rinse your eye with warm water. Do not put in any more drops

until it is time for your next regular dose.

You may experience a decreased heart rate, decreased blood pressure, heart failure, difficulty breathing and your nervous system may be affected.

While you are using AZARGA

Things you must do

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

If you are changing from another eye drop medicine used to treat glaucoma to Azarga, you should stop using the other medicine and start using Azarga the following day. Check with your doctor or pharmacist if you are not sure.

To prevent contamination of the dropper tip and the suspension, care must be taken not to touch the eyelids, surrounding areas or other surfaces with the dropper tip. Keep the bottle tightly closed when not in use.

The following measure is useful to limit the amount of medicine that will come into the blood after application of eye drops:

- Keep the eyelid closed, while simultaneously applying gentle pressure to the corner of the eye next to the nose with a finger for at least 2 minutes.

Only use Azarga for dropping in your eye(s).

If a drop misses your eye, try again.

If you are using other eye drop or eye ointment medicines, leave at least 5 minutes between each medicine. Eye ointments should be administered last.

Things you must not do

Do not stop using the medicine unless advised by your doctor. Do not give Azarga to anyone else, even if they

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have the same symptoms or condition as you.

Things to be careful of

If signs of serious reactions or hypersensitivity occur, discontinue the use of this product and talk to your doctor.

Do not drive or use machines until your vision is clear. You may find your vision is blurred for some time just after using Azarga.

One of the active ingredients may impair the ability to perform tasks requiring mental alertness and/or physical coordination. If affected take care when driving or using machines.

Side effects of AZARGA

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

Stop using Azarga and seek medical attention immediately if you notice any of the following symptoms:

- severe redness and itching of the eye, reddish non-elevated, target-like or circular patches on the trunk, 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).

You can usually carry on taking the drops, unless the effects are serious. If you are worried, talk to your doctor or pharmacist. Do not stop using Azarga without speaking to your doctor first.

Common (may affect up to 1 in 10 people):

- effects in the eye: eye surface inflammation, blurred vision, signs and symptoms of eye irritation (e.g. burning, stinging, itching, tearing, redness), eye pain

- general side effects: heart rate decreased, taste disturbances

Uncommon (may affect up to 1 in 100 people):

- effects in the eye: corneal erosion (damage to the front layer of the eyeball), eye surface inflammation with surface damage, inflammation inside the eye, corneal staining, abnormal sensation in the eye, eye discharge, dry eye, tired eyes, itchy eye, eye redness, eyelid redness.
- general side effects: decrease in white blood cell count, decreased blood pressure, cough, blood in urine, body weakness

Rare (may affect up to 1 in 1000 people):

- effects in the eye: corneal disorder, sensitivity to light, increased tear production, eyelid crusting
- general side effects: difficulty sleeping, throat pain, running nose

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of AZARGA

Storage

Do not store above 30°C.

Keep out the reach and sight of children.

Discard 4 weeks after first opening.

Disposal

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

What it looks like

Azarga is a white to off-white uniform suspension supplied in a 5ml bottle with a dispensing plug and screw cap.

Ingredients

- Active ingredient(s)

Brinzolamide 10mg/ml and
Timolol 5mg/ml

- Inactive ingredients

Benzalkonium chloride 0.1mg/ml, mannitol, carbomer 974P, tyloxapol, disodium edetate, sodium chloride, hydrochloric acid and/or sodium hydroxide (for pH adjustment), purified water.

MAL number:

MAL20091944ARZ

Manufacturer

Novartis Manufacturing N.V.
Rijksweg 14,
2870 Puurs-Sint-Amunds
Belgium

Product Registration Holder

Novartis Corporation (M) Sdn. Bhd.
Level 18, Imazium,
No. 8, Jalan SS21/37,
Damansara Uptown,
47400 Petaling Jaya, Selangor

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