

Regulatory Affairs

**AZARGA<sup>®</sup>** (brinzolamide / timolol)  
10 mg/mL brinzolamide / 5 mg/mL timolol  
Eye drops, Suspension

**Basic Patient Leaflet (BPL)**

**Version 4.0**

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**Read all of this leaflet carefully before you start using this medicine.**

Keep this leaflet. You may need to read it again.

This medicine has been prescribed for you only. Do not use it for any other illnesses; do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

If any of the side effects affects you severely or if you notice any side effects not listed in this leaflet, please talk to your doctor, pharmacist or healthcare provider.

If you have any further questions, ask your doctor, pharmacist or healthcare provider.

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**1 What AZARGA<sup>®</sup> is and what it is used for**

**What Azarga<sup>®</sup> is**

Azarga, eye drops suspension, contains the active substances brinzolamide and timolol maleate, which belong to a group of medicines called anti-glaucoma agents.

**What Azarga is used for**

Azarga is used to lower high pressure inside the eye(s) (intraocular pressure - IOP) in adult patients with open-angle glaucoma or hypertension (high pressure) in the eye who did not get effective treatment with other medicines. Azarga is prescribed if your physician considers it appropriate for you and your condition.

**How Azarga works**

Azarga is a combination of two active substances, brinzolamide and timolol. Brinzolamide belongs to a group of medicines called carbonic anhydrase inhibitors. Brinzolamide lowers the pressure in your eye(s) by reducing the production of fluid within the eye.

Timolol (timolol maleate) belongs to a group of medicines called beta-receptor blockers. Timolol lowers the pressure in your eye(s) by reducing the production of fluid within the eye.

If you have any questions about how Azarga works or why this medicine has been prescribed for you, ask your doctor, pharmacist, or healthcare provider.

## 2 What you need to know before and while you use Azarga

Follow all your doctor's instructions carefully. They may differ from the general information contained in this leaflet.

### Do not use Azarga

- If you are allergic to brinzolamide, timolol, or any of the other ingredients of this medicine. If you think you may be allergic, ask your doctor or healthcare provider for advice.
- If you are allergic to medicines called sulphonamides. Examples include medicines used to treat diabetes, infections and also diuretics (water tablets). Azarga may cause an 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 a slow heartbeat, heart failure or disorders of heart rhythm (irregular heartbeats).
- If you have severe kidney problems.
- If you have too much acidity in your blood (a condition called hyperchloraemic acidosis).

### Warnings and precautions

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

Talk to your doctor or healthcare provider before using Azarga, if you have now 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/irregular heart rate
- 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
- Myasthenia gravis (chronic neuromuscular weakness)
- Any severe allergic reaction (skin rash, redness and itching of the eye) while you are using Azarga, whatever the cause, since adrenaline (epinephrine) treatment may not be as effective. So, when receiving any other treatment please tell your doctor or healthcare provider that you are taking Azarga
- If you have a disease of the surface of your eye (cornea)
- Kidney problems

- Tell your doctor or healthcare provider before you have an operation that you are using Azarga as timolol may change effects of some medicines used during anaesthesia.

### **Children and adolescents (below 18 years)**

Azarga is not to be used in children or adolescents (below 18 years).

### **Taking other medicines (interactions with other medicinal products including vaccines or biologics)**

Azarga can affect or be affected by other medicines you are using, including other eye drops for the treatment of glaucoma.

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

- Medicines to lower blood pressure, to control heart rate, to treat heart failure, or those that stimulate a part of the nervous system (parasympathetic). This may lead to decrease in blood pressure or heart rate.
- Medicines that affect metabolism of timolol including quinidine (used to treat heart conditions and some types of malaria), or antidepressants known as fluoxetine and paroxetine. These medicines may enhance the effect of beta blockers that may result in decreased heart rate or depression.
- Pupil dilation has been reported occasionally when used at the same time with adrenaline (epinephrine).
- Similarly, timolol may affect treatment with other medications. Other products in the same class of this medicine can decrease the response to adrenaline (epinephrine) to treat severe allergic reactions.
- If you are taking another carbonic anhydrase inhibitor (acetazolamide or dorzolamide) or medicines that are NSAIDs or salicylates, talk to your doctor or healthcare provider.

### **Pregnancy and breast-feeding**

Do not use Azarga if you are pregnant unless your doctor or healthcare provider considers it necessary.

If you are breast-feeding, ask your doctor or healthcare provider for advice before taking Azarga. Timolol passes into human milk.

### **Important information about some of the ingredients of Azarga**

Azarga contains benzalkonium chloride.

- A preservative in Azarga (benzalkonium chloride) may cause eye irritation and is also known to discolor soft contact lenses.
- If you wear contact lenses you should remove them before using Azarga and wait at least 15 minutes before putting your lenses back in.

### 3 How to use Azarga

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

- Do not exceed the recommended dose prescribed by your doctor or healthcare provider.
- Shake the bottle well before use
- Only use Azarga for dropping in your eye(s). After cap is removed, if tamper evident snap collar is loose, remove before using product.
- To avoid contamination, the dropper tip should not touch any surface. The dropper tip should also not come into contact with the eye as this may cause injury to the eye. Keep the bottle tightly closed when not in use.
- After using Azarga, close your eyelids and press a finger into the corner of your eye, by the nose for 2 minutes. This helps to stop Azarga getting into the rest of the body and increases the effect in the eye.
- When substituting another ophthalmic antiglaucoma medication with Azarga, the other medication should be discontinued, and Azarga should be started the following day.

**If a drop misses your eye, try again.**

**In case of accidental ingestion, contact your doctor or healthcare provider.** Possible symptoms of overdose include decreased heart rate, decreased blood pressure, heart failure, difficulty breathing and may affect your nervous system.

**If you forget to use Azarga** continue with the next dose as planned. The dose should not exceed one drop in the affected eye(s) twice daily. **Do not** use a double dose to make up.

**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.

**If you have any further questions on the use of this medicine, ask your doctor, pharmacist, or healthcare provider.**

### 4 Possible side effects

As with all medicines, patients treated with Azarga may experience side effects, although not everybody gets them.

If you experience any of these side effects, tell your doctor, pharmacist, or healthcare provider.

**Common:** *may affect up to 1 in every 10 people*

- Effects in the eye: eye surface inflammation, blurred vision, eye pain, eye irritation
- General side effects: heart rate decreased, bad taste

**Uncommon:** *may affect up to 1 in every 100 people*

- Effects in the eye: eye surface inflammation with surface damage, corneal staining, dry eye, itchy eye, eye redness, eyelid redness, abnormal sensation in the eye, eye discharge
- General side effects: decrease in white blood cell count, decreased blood pressure, blood in urine, cough, body weakness

**Rare:** *may affect up to 1 in every 1,000 people*

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

**Not known:** *frequency cannot be estimated from the available data*

- Effects in the eye: visual impairment, eye allergy, eyelid swelling, inflammation of the conjunctiva (white of the eye)
- General side effects: severe allergic reaction, asthma, allergy (hypersensitivity), increased blood pressure, shortness of breath, depression, abnormal increase in heart rate, diarrhea, nose bleeds, chest pain, dry mouth, nausea, fatigue, muscle pain, skin redness, feeling or hearing things that are not there (hallucination), dizziness, headache, abdominal discomfort, loss of hair, rash, itching, abnormal skin sensation, ringing in ears.

## 5 How to store Azarga

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date.
- This medicinal product does not require any special storage conditions.

Country-specific

Information might differ in some countries.

## 6 Contents of the pack and other information

### What Azarga contains

The **active substances** of Azarga are brinzolamide and timolol maleate.

The **other excipients** of Azarga are benzalkonium chloride, disodium edetate, sodium chloride, tyloxapol, mannitol, carbomer 974P, sodium hydroxide and/or hydrochloric acid (to adjust pH), and purified water.

This information might differ in some countries.

### What Azarga looks like and contents of the pack

Azarga is supplied as Eye Drops, suspension.

It is supplied in round low-density polyethylene (LDPE) bottles with an LDPE dispensing plug and a polypropylene (PP) screw cap.

Following fill volumes are available: 2.5 mL, 5 mL, 6 mL. For some of these fill volumes, outer cartons containing 1 or 3 bottles are available. Not all pack sizes may be marketed.

This information might differ in some countries.

### **Marketing authorization holder**

{Name and address}

<Tel>

<Fax>

<E-mail>

Country-specific.

*This section is to be completed nationally as per local requirements.*

### **Manufacturer**

{Name and address}

Country-specific.

*This section is to be completed nationally.*

Country-specific.

This leaflet was last <revised> <approved> on:

<Month YYYY>

## 7 BPL History Table

Version	Effective date	GLC/PSB approval date	SLC Tracking No.	Section keyword	Authors GLM/GPRD/ GPRM
1.0	25-Mar-2016	N/A	ALCON TDOC-0016184 v1.0	BPL Creation	J. Shankardas
2.0	07-Jun-2016	N/A	ALCON TDOC-0016184 v2.0	Section 2: Updated warnings and precautions (removal of dry eyes) and other medicines and Azarga (removal of gastric ulcers and addition of text on epinephrine).  Section 3: addition of how to use information.  Section 4: addition and removal of ADRs for consistency with the CDS changes.	A. Mukerjee
2.1	04-Jun-2020	05-May-2020	2020-PSB/GLC-1102-s	Addition of hallucination as ADR.	R. Falen
4.0	05-Nov-2020	22-Sep-2020	N/A	Update – BPL converted from Alcon to Novartis template. Creation of sections 1,5, and 6. Addition of benzalkonium chloride and contact lenses text into the W&P section. Rewording of section "Taking other medicines". Removal of "Driving and using machines" section. Rewording of "How to use Azarga" section.  Version 3.0 was skipped, to use the same version number as the CDS.	R. Falen