NOVARTIS

AZARGA®

(brinzolamide/timolol maleate)

brinzolamide 10 mg/ml / timolol 5 mg/ml eye drops suspension

Patient Information Leaflet

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SCHEDULING STATUS

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

AZARGA Eye Drops, suspension

Read all of this leaflet carefully before you start using AZARGA.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- AZARGA has been prescribed for you personally. Do not pass it on to others. It may harm them even if their symptoms are the same as yours.
- If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

WHAT AZARGA CONTAINS

The active substances are: **brinzolamide and timolol.** 1 ml of suspension contains 10 mg brinzolamide and 5 mg timolol (as timolol maleate).

The other ingredients are: benzalkonium chloride (preservative), carbopol 974P, disodium edetate, mannitol (E421), purified water, sodium chloride and tyloxapol.

Contains sugar (mannitol).

WHAT AZARGA IS USED FOR

AZARGA is used to treat high pressure in the eye. This pressure can lead to a condition called glaucoma. AZARGA is a combination of treatments for glaucoma.

It contains two active substances which work together to reduce pressure within the eye.

BEFORE YOU USE AZARGA

Do not use AZARGA

- if you are allergic to brinzolamide, timolol or to any of the excipients.
- if you have respiratory problems such as asthma, bronchitis or other types of breathing problems
- if you have a slow heartbeat, heart failure or disorders of heart rhythm
- if you have severe hay fever and hyper reactivity of lungs and bronchial tubes
- if you have too much acidity in your blood (a condition called hyperchloraemic acidosis)
- if you have severe kidney problems
- if you are allergic to sulphonamides
- if you are pregnant or breastfeeding your baby.

Take special care with AZARGA

- if you have angina (chest pains), circulation problems or low blood pressure AZARGA may make any of these worse. If you experience any changes in these symptoms, tell your doctor as soon as possible
- if you get any severe allergic reaction while you are using AZARGA, whatever the cause, epinephrine (adrenaline) treatment may not be as effective. So, when receiving any other treatment please tell the health professional that you are taking AZARGA
- if you have diabetes AZARGA can mask the symptoms of low blood sugar (hypoglycaemia) such as shakiness and dizziness, so you need to use it with care
- if you have hyperthyroidism (overactive thyroid gland)
- if you suffer from muscle weakness AZARGA may make it worse
- if you have liver problems, talk to your doctor
- if you have dry eyes or cornea problems, talk to your doctor
- if you have coronary heart disease (symptoms can include chest pain or tightness, breathlessness or choking), heart failure, low blood pressure, talk to your doctor
- if you have poor blood circulation disease (such as Raynaud’s disease or Raynaud’s syndrome), talk to your doctor
- tell your doctor before you have an operation that you are using AZARGA as timolol may change effects of some medicines used during anaesthesia.

- AZARGA is not recommended for children under 18 years.

Pregnancy and breastfeeding

Safety and efficacy have not been established.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

You should not use AZARGA if you are pregnant or might get pregnant.

However, if you do use AZARGA until your baby is born, your doctor will monitor your baby carefully during the first days of life.

You should not breastfeed your baby if you are using AZARGA.

If you are breastfeeding, you should not use AZARGA as studies have shown that its active ingredients are excreted in breast milk and could cause serious side effects in the infant.

Driving and using machines

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

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.

Important information about some of the ingredients of AZARGA

There is a preservative in AZARGA (benzalkonium chloride) that can discolour soft lenses and may cause eye irritation or damage. Therefore, do not wear contact lenses whilst using AZARGA. Wait 15 minutes after using AZARGA before putting your lenses back in.

Using other medicines with AZARGA

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

AZARGA can affect or be affected by other medicines you are taking, including other eye drops for the treatment of glaucoma. Tell your doctor if you are taking or intend to take medicines to lower blood pressure, heart medicines, medicines to treat diabetes, medicines to treat gastric ulcers or antifungal, antiviral or antibiotic medicines.

HOW TO USE AZARGA

Do not share medicines prescribed for you with any other person.

Always use AZARGA exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose is:

Adults: One drop in the affected eye or eyes, twice a day - morning and night.

Only use AZARGA in both eyes if your doctor told you to. Use it for as long as your doctor told you to.


1


2


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- Get the AZARGA bottle and a mirror.
- Wash your hands.
- Shake the bottle well before use.
- Twist off the bottle cap.
- 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 gently into the corner of your eye, by the nose (picture 3) for 2 minutes. 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.

If a drop misses your eye, try again.

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.

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

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 are using other eye drops, wait at least 5 minutes between using AZARGA and the other drops.

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

POSSIBLE SIDE EFFECTS

AZARGA can have side effects.

Not all side effects reported for AZARGA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking AZARGA and tell your doctor immediately or go to the casualty department at your nearest hospital (frequency not known):

- skin rash
- severe skin reactions
- severe redness and itching of the eye

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to AZARGA. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent Side Effects:

dysgeusia, blurred vision, eye irritation and eye pain.

Less Frequent Side Effects:

insomnia, corneal erosion, punctate keratitis, dry eye, eye discharge, eye pruritus, ocular hyperaemia, blepharitis, allergic conjunctivitis, corneal disorder, anterior chamber flare, conjunctival hyperaemia, eyelid margin crusting, asthenopia, abnormal sensation in eye, eyelids pruritus, allergic blepharitis, erythema of eyelid, foreign body sensation in eyes, photophobia, lacrimation increased, scleral hyperaemia, decreased blood pressure, chronic obstructive pulmonary disease, pharyngolaryngeal pain, cough, rhinorrhoea, hair disorder and lichen planus.

Side Effects with Frequency Unknown:

nasopharyngitis, pharyngitis, sinusitis, rhinitis, red blood cell count decreased, blood chloride increased, hypersensitivity, hypoglycaemia, apathy, depression, depressed mood, libido decreased, nightmare, nervousness, somnolence, motor dysfunction, amnesia, memory impairment, dizziness, paraesthesia, tremor, headache, hypoaesthesia, ageusia, cerebral ischaemia, cerebrovascular accident, syncope, myasthenia gravis, keratitis, keratopathy, increased optic nerve cup/disc ratio, corneal epithelium defect, corneal epithelium disorder, increased intraocular pressure, eye deposit, corneal staining, corneal oedema, conjunctivitis,

meibomianitis, diplopia, glare, photophobia, photopsia, reduced visual acuity, pterygium, ocular discomfort, keratoconjunctivitis sicca, hypoaesthesia of the eye, scleral pigmentation, subconjunctival cyst, increased lacrimation, visual disturbance, eye swelling, eye allergy, madarosis, eyelid disorder, eyelid oedema, eyelid ptosis, tinnitus, vertigo, cardio-respiratory distress, angina pectoris, bradycardia, irregular heart rate, dysrhythmia, palpitations, tachycardia, increased heart rate, cardiac arrest, cardiac failure, atrioventricular block, Increased blood pressure, hypertension, hypotension, dyspnoea, asthma, bronchial hyperactivity, epistaxis, throat irritation, nasal congestion, upper respiratory tract congestion, postnasal drip, sneezing, nasal dryness, respiratory failure, bronchospasm, dry mouth, oesophagitis, vomiting, diarrhoea, nausea, dyspepsia, upper abdominal pain, abdominal discomfort, stomach discomfort, frequent bowel movements, gastrointestinal disorder, oral hypoaesthesia, oral paraesthesia, flatulence, abnormal liver function test, urticaria, maculo-papular rash, rash, generalised pruritus, alopecia, skin tightness, dermatitis, erythema, back pain, muscle spasms, myalgia, arthralgia, pain in extremity, renal pain, pollakiuria, erectile dysfunction, pain, asthenia chest discomfort, , fatigue, feeling abnormal, feeling jittery, irritability, chest pain, peripheral oedema, malaise, medication residue and foreign body in eye.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF AZARGA

Store all medicines out of reach of children.

Do not use AZARGA after the expiry date which is stated on the bottle and the carton after EXP. The expiry date refers to the last day of that month.

Store the bottle in a cool, dry place at or below 30 °C.

Throw the bottle away 4 weeks after first opening to prevent infections and use a new bottle. Write down the date of opening on the bottle label and carton label in the space provided.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines you no longer require. These measures will help protect the environment.

PRESENTATION OF AZARGA

Round opaque low density polyethylene bottles with a dispensing plug and white polypropylene screw cap containing 5 ml suspension, packaged inside an outer carton.

IDENTIFICATION OF AZARGA

White to off-white uniform suspension.

REGISTRATION NUMBER

44/15.4/0046

NAME AND ADDRESS OF REGISTRATION HOLDER

Novartis South Africa (Pty) Ltd

Magwa Crescent West Waterfall City

Jukskei View

2090

DATE OF PUBLICATION

The date on the registration certificate of the medicine

02 March 2012

The date of the most recently revised package insert as approved by Council

20 March 2018