EMA/190551/2014
EMEA/H/C/000960

EPAR summary for the public

Azarga

brinzolamide / timolol

This is a summary of the European public assessment report (EPAR) for Azarga. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Azarga.

What is Azarga?

Azarga is a medicine that contains two active substances, brinzolamide and timolol. It is available as eye drops.

What is Azarga used for?

Azarga is used to reduce intra-ocular pressure (IOP, pressure inside the eye). It is used in adults with open-angle glaucoma (a disease where the pressure in the eye rises because fluid cannot drain out of the eye) or ocular hypertension (when the pressure in the eye is higher than normal). Azarga is used when treatment with a medicine containing only one active substance has been tried but has not reduced the IOP sufficiently.

The medicine can only be obtained with a prescription.

How is Azarga used?

Azarga is given as one drop into the affected eye(s) twice a day. The suspension needs to be shaken well before use. If it is used with another eye medicine, the different medicines should be used at least 5 minutes apart. If the other eye medicine is an eye ointment it should be used last.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

How does Azarga work?

Raised IOP causes damage to the retina (the light-sensitive surface at the back of the eye) and to the optic nerve that sends signals from the eye to the brain. This can result in serious vision loss and even blindness. By lowering the pressure, Azarga reduces the risk of damage.

Azarga contains two active substances, brinzolamide and timolol. The two substances work by reducing the production of the aqueous humour (the watery fluid in the eye) in different ways. Brinzolamide is a carbonic anhydrase inhibitor that works by blocking an enzyme called carbonic anhydrase, which produces bicarbonate ions in the body. Bicarbonate is required for the production of the aqueous humour. Brinzolamide has been authorised in the European Union (EU) as Azopt since 2000. Timolol is a beta blocker that has been commonly used to treat glaucoma since the 1970s. The combination of the two active substances has an additive effect, reducing the pressure inside the eye more than either medicine alone.

How has Azarga been studied?

Azarga has been studied in two main studies involving a total of 960 adults with open-angle glaucoma or ocular hypertension. The first was a six-month study comparing Azarga with brinzolamide and with timolol used on their own in 523 patients. The second was a 12-month study comparing Azarga with the combination of timolol and dorzolamide (another carbonic anhydrase inhibitor) in 437 patients. In both studies, the main measure of effectiveness was the change in IOP over the first six months of treatment. IOP was measured in 'millimetres of mercury' (mmHg).

What benefit has Azarga shown during the studies?

Azarga was more effective than either of the active substances used alone and was as effective as the combination of timolol and dorzolamide. In the first study, IOP fell from around 21 mmHg by 8.0 to 8.7 mmHg in the patients using Azarga. This compared with 5.1 to 5.6 mmHg in those using brinzolamide and 5.7 to 6.9 mmHg in those using timolol. In the second study, IOP had fallen from around 26 mmHg by around 8.3 mmHg after six months in both groups of patients.

What is the risk associated with Azarga?

The most common side effects with Azarga (seen in between 1 and 10 patients in 100) are blurred vision, eye pain and eye irritation. For the full list of all side effects reported with Azarga, see the package leaflet.

Azarga must not be used in patients who are hypersensitive (allergic) to the active substances, any of the other ingredients, other beta blockers (such as some heart medicines) or sulphonamides (an antibiotic). It must not be used by patients who:

- have or have had asthma;
- have severe chronic obstructive pulmonary disease (COPD, a disease causing narrowing of the airways);
- have certain heart problems;
- have a severe allergic rhinitis (allergy affecting the nose and airways);
- have hyperchloraemic acidosis (excess acid in the blood caused by too much chloride);
- have severely reduced kidney function.

For the full list of restrictions, see the package leaflet.

Azarga contains benzalkonium chloride, which is known to discolour soft contact lenses. Therefore, care should be taken by people who wear soft contact lenses.

Why has Azarga been approved?

The Committee for Medicinal Products for Human Use (CHMP) noted that combining the two active substances in Azarga simplifies therapy and helps patients to stick to their treatment. The Committee decided that Azarga's benefits are greater than its risks and recommended that it be given marketing authorisation.

What measures are being taken to ensure the safe and effective use of Azarga?

A risk management plan has been developed to ensure that Azarga is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Azarga, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Azarga

The European Commission granted a marketing authorisation valid throughout the EU for Azarga on 25 November 2008. The full EPAR for Azarga can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Azarga, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 03-2014.