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EPAR summary for the public

Azopt

brinzolamide

This is a summary of the European public assessment report (EPAR) for Azopt. 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 Azopt.

What is Azopt?

Azopt is a medicine that contains the active substance brinzolamide. It is available as an eye drop suspension.

What is Azopt used for?

Azopt is used to reduce the pressure inside the eye. It is used in patients with ocular hypertension (when the pressure in the eye is higher than normal) or open-angle glaucoma (a disease in which the pressure inside the eye rises because fluid cannot drain out of the eye). Azopt is used as an add-on to beta blockers or prostaglandin analogues (other medicines used for these conditions), or on its own in patients who cannot take or do not respond to beta blockers.

The medicine can only be obtained with a prescription.

How is Azopt used?

The dose of Azopt is one drop into the affected eye(s) twice a day. Some patients may have a better response with one drop three times a day. The suspension needs to be shaken before use. If more than one type of eye-drop medicine is being used, each one should be given at least five minutes apart.

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How does Azopt work?

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

The active substance in Azopt, brinzolamide, is a carbonic anhydrase inhibitor. It works by blocking an enzyme called carbonic anhydrase, which produces bicarbonate in the body. Bicarbonate is required for the production of the aqueous humour (the watery fluid in the eye). By blocking the production of bicarbonate in the eye, Azopt slows down the production of aqueous humour, reducing the pressure inside the eye.

How has Azopt been studied?

Azopt has been studied in seven main studies including a total of 2,173 patients with open-angle glaucoma or ocular hypertension.

In three of the studies, Azopt, used on its own two or three times a day, was compared with timolol (a beta-blocker) and with dorzolamide (another carbonic anhydrase inhibitor). Two of the studies compared adding Azopt, dorzolamide or placebo (a dummy treatment) to timolol, and the final two studies compared Azopt used twice a day with timolol, when they were used as an add-on to travoprost (a prostaglandin analogue). All of the studies lasted for three months, except for the study comparing Azopt used on its own with timolol, which lasted for 18 months.

In all of the studies, the main measure of effectiveness was the change in pressure inside the eye, measured in units called 'millimetres of mercury' (mmHg). The eye pressure was at least 21 mmHg in all of the patients at the start of the studies (above the normal range of 10 to 21 mmHg).

What benefit has Azopt shown during the studies?

When used on its own, Azopt was less effective than timolol. Azopt caused a reduction in eye pressure of between 2.7 and 5.7 mmHg over 18 months, compared with a reduction of between 5.2 and 6.0 mmHg with timolol.

Azopt was as effective as dorzolamide when used on its own or as an add-on to timolol, with decreases in pressure of between 3.4 and 5.7 mmHg. Dorzolamide led to decreases of between 4.3 and 4.9 mmHg. Azopt was also more effective than placebo when used as an add-on to timolol.

When used as an add-on to travoprost, Azopt had a similar effect to timolol in reducing eye pressure. In both studies, adding either Azopt or timolol caused a further decrease in eye pressure of around 3.5 mmHg after 12 weeks.

Overall, Azopt showed a similar effect when used two or three times a day. However, the results suggested that some patients may show a greater reduction in eye pressure when using the drops three times a day.

What is the risk associated with Azopt?

The most common side effects with Azopt (seen in more than 1 patient in 20) are dysgeusia (a bitter or unusual taste in the mouth) and temporary blurring of vision. For the full list of all side effects reported with Azopt, see the package leaflet.

Azopt must not be used in people who are hypersensitive (allergic) to brinzolamide or any of the other ingredients, or to other medicines called sulphonamides (such as some antibiotics). It must not be used in patients with severe kidney disease or hyperchloraemic acidosis (excess acid in the blood caused by too much chloride). For the full list of restrictions, see the package leaflet.

Why has Azopt been approved?

The Committee for Medicinal Products for Human Use (CHMP) decided that Azopt'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 Azopt?

A risk management plan has been developed to ensure that Azopt 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 Azopt, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Azopt

The European Commission granted a marketing authorisation valid throughout the European Union for Azopt on 9 March 2000.

The full EPAR for Azopt 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 Azopt, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 05-2014.