Summary Public Assessment Report

non-generics

Brinzolamide Actavis 10 mg/ml eye drops, suspension

(brinzolamide)

NL/H/2973/001/DC

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Active substance: brinzolamide

This is a summary of the public assessment report (PAR) for Brinzolamide Actavis 10 mg/ml eye drops, suspension. It explains how this product was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Brinzolamide Actavis.

For practical information about using Brinzolamide Actavis, patients should read the package leaflet or contact their doctor or pharmacist.

What is Brinzolamide Actavis and what is it used for?
Brinzolamide Actavis 10 mg/ml is a 'hybrid generic medicine'. This means that it is similar to a reference medicine containing the same active substance, Azopt 10 mg/ml eye drops, suspension. The product acts locally in the eye, and is not absorbed in the body. This means that levels in the blood cannot be measured for direct comparison of Brinzolamide Actavis and Azopt 10 mg/ml eye drops, suspension. This is why the term hybrid is used. The company conducted a study to demonstrate that the two medicines work equally well.

This medicine 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). Brinzolamide Actavis 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.

How does this medicine 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, this medicine reduces the risk of damage to these structures.
The active substance, 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, Brinzolamide Actavis slows down the production of aqueous humour, reducing the pressure inside the eye.

How is this medicine used?
This suspension has nearly the same composition of the active substance and the excipients as the reference product. However, Azopt contains one additional excipient: tyloxapol. The company conducted a study to show that this difference in the composition does not affect the efficacy. In this study subjects with high pressure inside the eye were administered the test product (Brinzolamide Actavis) and the reference product (Azopt). Both medicines showed similar results in reducing eye pressure. The safety of use was also comparable. This means that the two medicines are therapeutically equivalent. The benefits and risks of Brinzolamide Actavis can be considered the same as those of the reference product.

What benefits of this medicine have been shown in studies?
Because Brinzolamide Actavis is a hybrid application and is considered to be therapeutically equivalent, to the reference product Azopt, their benefits and risks are taken as being the same as those of the reference medicine.

What are the possible side effects from this medicine?
The most common side effects with Brinzolamide Actavis (which may affect up to 1 in 10 people) are the following effects to the eye: blurred vision, eye irritation, eye pain, eye discharge, itchy eye, dry eye, abnormal eye sensation, or redness of the eye. A general side effect is bad taste.

For the full list of all side effects reported with this medicine, see section 4 of the package leaflet.

Why is this medicine approved?
The Medicines Evaluation Board of the Netherlands decided that the benefits of Brinzolamide Actavis are greater than its risks and recommended that it be approved for use.

What measures are being taken to ensure the safe and effective use of Brinzolamide Actavis?
A risk management plan has been developed to ensure that Brinzolamide Actavis 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 Brinzolamide Actavis, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored.

Other information about this medicine
The marketing authorisation for Brinzolamide Actavis 10 mg/ml eye drops, suspension was granted on 28 December 2015.
The full PAR for Brinzolamide Actavis can be found on the website http://mri.medagencies.org/Human. For more information about treatment with this medicine, read the package leaflet (http://mri.medagencies.org/download/NL_H_2973_001_FinalPL.pdf) or contact your doctor or pharmacist.

This summary was last updated in November 2016.