LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Brintidox
(brinzolamide and timolol maleate)

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Brinzolamide, timolol maleate

Eye drops, suspension, 10 mg/ml + 5 mg/ml

This is a summary of the public assessment report (PAR) for Brintidox. It explains how Brintidox 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 Brintidox.

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

What is Brintidox and what is it used for?

Brintidox is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substances. The company has provided additional own data to demonstrate therapeutic equivalence between Brintidox and the reference medicine.

The reference medicine for Brintidox is AZARGA. Brintidox used to treat high pressure in the eyes, also called glaucoma or ocular hypertension (a disease where the pressure in the eye rises because fluid cannot drain out of the eye), in adult patients that are more than 18 years of age and in whom high pressure in the eyes cannot be controlled effectively by one medicine alone.

How does Brintidox work?

Brintidox contains two active substances, brinzolamide and timolol, which work together to reduce pressure within the eye. The two substances work by reducing the production of the aqueous humour (the watery fluid in the eye) in different ways. The combination of the two active substances has an additive effect, reducing the pressure inside the eye more than either medicine alone.

How is Brintidox used?

The pharmaceutical form of Brintidox is eye drops, suspension, for ocular use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

What benefits of Brintidox have been shown in studies?

Because Brintidox is a hybrid application and is considered to be therapeutically equivalent, to the reference product AZARGA, their benefits and risks are taken as being the same as those of the reference medicine.

What are the possible side effects of Brintidox?

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

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

Why is Brintidox approved?

This medicine is similar to a reference medicine containing the same active substances. The company has provided own data to demonstrate therapeutic equivalence between Brintidox and the reference medicine.
No new or unexpected safety concerns arose from the application. Therefore, the Medical Products Agency in Sweden decided that Brintidox's benefits 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 Brintidox?

A risk management plan has been developed to ensure that Brintidox 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 Brintidox, 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/reviewed continuously as well.

Other information about Brintidox

The full PAR for Brintidox can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Brintidox, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2020-02.