LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Brimonidin Bluefish
(brimonidine tartrate)

SE/H/1600/01/DC

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(brimonidine tartrate)

Eye drops, solution, 2 mg/ml

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

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

What is Brimonidin Bluefish, how does it work and what is it used for?

Brimonidin Bluefish is a 'hybrid medicine'. This means that Brimonidin Bluefish is similar to a 'reference medicine' already authorised in the European Union (EU) called Alphagan.

Brimonidin Bluefish works by reducing pressure within the eyeball in the conditions open angle glaucoma or ocular hypertension. It can be used either alone or with another eye drop, if a single medicine is not enough to lower the increased pressure in the eye.

How is Brimonidin Bluefish used?

The pharmaceutical form of Brimonidin Bluefish is eye drop, solution.

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 Brimonidin Bluefish have been shown in studies?

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

What are the possible side effects of Brimonidin Bluefish?

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

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

Why is Brimonidin Bluefish approved?

This medicine is similar to a reference medicine containing the same active substance.
No new or unexpected safety concerns arose from the application. Therefore, the Medical

Products Agency in Sweden decided that Brimonidin Bluefish'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 Brimonidin Bluefish?

A risk management plan has been developed to ensure that Brimonidin Bluefish 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 Brimonidin Bluefish, 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 Brimonidin Bluefish

The marketing authorisation for Brimonidin Bluefish was granted on 2016-11-11 in Sweden.

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

This summary was last updated in 2016-11.