

Summary Public Assessment Report

Bimabloc (bimatoprost, timolol maleate)

SE/H/2400/001/DC

Summary Public Assessment Report

Bimabloc
bimatoprost, timolol maleate

eye drops, solution, 0.3 mg/ml + 5 mg/ml

This is a summary of the public assessment report (PAR) for Bimabloc. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Bimabloc and what is it used for?

The product is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance available as eye drops, solution.

The reference medicine for the product is GANFORT.

The company has provided additional own data to demonstrate therapeutic equivalence between the product and the reference medicine.

The product contains two different active substances (bimatoprost and timolol) that both reduce pressure in the eye. Bimatoprost belongs to a group of medicines called prostamides, a prostaglandin analogue. Timolol belongs to a group of medicines called beta-blockers.

High pressure in eyes can lead to glaucoma (damaged sight). The product is used to treat high pressure in eyes of adults including elderly.

How does Bimabloc work?

The eye contains a clear watery liquid that feeds its inside. Liquid is constantly being drained out of the eye and new liquid is made to replace this. If the liquid cannot be drained quickly enough, pressure builds up inside and could eventually damage the sight and cause glaucoma. The product works by reducing the production of liquid and also increasing the liquid drainage. This reduces the pressure inside the eye.

The two components (bimatoprost and timolol) decrease elevated intraocular pressure (IOP) by complementary mechanisms of action and the combined effect results in additional IOP reduction compared to either compound administered alone. The combination of these two components has a rapid onset of action. The product is therefore prescribed when other eye drops containing beta-blockers or prostaglandin analogues have not worked sufficiently on their own.

How is Bimabloc used?

The pharmaceutical form is *eye drops, solution*, intended 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 in Sweden.

What benefits of Bimabloc have been shown in studies?

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

What are the possible side effects from Bimabloc?

For the full list of side effects, see section 4 of the package leaflet.

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

Why is Bimabloc approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered therapeutically equivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for GANFORT, the benefits are greater than its risks and recommended that it can be approved for use.

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

A risk management plan has been developed to ensure that the product 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, 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 Bimabloc

The full PAR for Bimabloc can be found on the following website:

<http://mri.medagencies.org/Human/>. For more information about treatment with Bimabloc, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2025-01.