LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Travabloc
(timolol maleate, travoprost, timolol)

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Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@lakemedelsverket.se

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Eye drops, solution, 40 mikrogram/ml + 5 mg/ml

This is a summary of the public assessment report (PAR) for Travabloc. 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 Travabloc 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 as the reference medicine.

The reference medicine for the product is DuoTrav.

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

Travabloc eye drops are used to treat high pressure in the eye in adults, including the elderly**.** This pressure can lead to an illness called glaucoma.

How does Travabloc work?

Travabloc eye drop solution is a combination of two active substances (travoprost and timolol). Travoprost is a prostaglandin analogue which works by increasing the outflow of aqueous fluid from the eye, which lowers its pressure. Timolol is a beta blocker which works by reducing the production of fluid within the eye. The two substances work together to reduce pressure within the eye.

How is Travabloc used?

The pharmaceutical form is Eye drops, 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 in Sweden.

What benefits of Travabloc have been shown in studies?

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

What are the possible side effects from Travabloc?

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 Travabloc approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be therapeutically equivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for DuoTrav, 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 Travabloc?

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 Travabloc

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

This summary was last updated in 2025-02.