LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Dorzolamid/Timolol Misom
(dorzolamide hydrochloride, timolol maleate)

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Eye drops, solution, 20 mg/ml + 5 mg/ml

This is a summary of the public assessment report (PAR) for Dorzolamid/Timolol Misom. 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 Dorzolamid/Timolol Misom 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.

The reference medicine for the product is Cosopt.

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

The product is used for treatment of raised eyeball pressure in glaucoma patients. Elevated eyeball pressure is a major risk factor in the development of optic nerve damage and visual field loss related to glaucoma.

How does Dorzolamid/Timolol Misom work?

The product lowers raised pressure in the eyeball in the treatment of glaucoma when beta-blocker eye drop medicine used alone is not sufficient.

The product is comprised of two components: dorzolamide hydrochloride and timolol maleate. Each of these decreases elevated pressure in the eyeball, whether or not associated with glaucoma. Their different mechanisms of action both result in reduced aqueous secretion into the chamber located in front of the pupil.

How is Dorzolamid/Timolol Misom used?

The pharmaceutical form is eye drops, solution 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 Dorzolamid/Timolol Misom have been shown in studies?

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

What are the possible side effects from Dorzolamid/Timolol Misom?

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 Dorzolamid/Timolol Misom approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered similar to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Cosopt, 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 Dorzolamid/Timolol Misom?

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 Dorzolamid/Timolol Misom

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

This summary was last updated in 2023-11.