Summary Public Assessment Report

Non-generics

Xaloptic 0.05 mg/ml eye drops, solution in unit dose container

(latanoprost)

NL/H/3193/001/DC

Date: 17 March 2015

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Active substance: latanoprost

This is a summary of the public assessment report (PAR) for Xaloptic 0.05 mg/ml eye drops. It explains how this medicine 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 this medicine.

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

What is this medicine and what is it used for?
Xaloptic is a 'hybrid medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Xalatan. The active substance latanoprost acts locally in the eye, and is not absorbed in the body. This means that the levels in blood cannot be measured for direct comparison of Xaloptic and Xalatan eye drops. This is why the term hybrid is used.
The two products contain the same active substance and excipients. In addition, Xalatan contains a preservative, benzalkonium chloride. Xaloptic does not, as it is intended for single use.

Xaloptic 0.05 mg/ml eye drops are used to treat conditions known as open angle glaucoma and ocular hypertension. Both of these conditions are linked with an increase in the pressure within the eye, eventually affecting the eye sight. It is also used to treat increased eye pressure and glaucoma in children and babies of all ages.

How does this medicine work?
This medicine contains latanoprost and it belongs to a group of medicines known as prostaglandin analogues. It works by increasing the natural outflow of fluid from inside the eye into the blood stream, thereby reducing the pressure within the eye.

How is this medicine used?
The pharmaceutical form of is eye drops and the route of administration is ocular (for use in the eye). The medicine can only be obtained with a prescription. The recommended dose is one drop once a day in the affected eye(s). The best time to do this is in the evening. The unit dose container must be used right after opening; any residual product must be discarded.

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

How has this medicine been studied?
As this medicine is a locally active product, no bioequivalence studies could be performed. It has the same composition of the active substance and the excipients as the reference product. The only difference between the two products is that the reference product contains a preservative and Xaloptic does not, but this does not affect the clinical efficacy or safety.
Xaloptic was registered as a hybrid medicinal product and because it is considered to be therapeutically equivalent to the reference product Xalatan eye drops, their benefits and risks can be considered the same.

What are the possible side effects of this medicine?
Because this is a hybrid medicine which is essentially similar to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine.
For the full list of all side effects reported with this medicine, see section 4 of the package leaflet.

Why is this medicine approved?
The Medicines Evaluation Board of the Netherlands decided that the benefits of Xaloptic eye drops 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 this medicine?
A risk management plan has been developed to ensure that this medicine 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 Xaloptic, 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 this medicine
In the Netherlands, the marketing authorisation for Xaloptic 0.05 mg/ml eye drops, solution in unit dose container was granted on 21 January 2015.

The full PAR for this medicine can be found on the website http://mri.medagencies.org/Human>. For more information about treatment with Xaloptic, read the package leaflet (http://mri.medagencies.org/download/NL_H_3193_001_FinalPL.pdf) or contact your doctor or pharmacist.

This summary was last updated in March 2015.