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Catiolanze (*latanoprost*)

An overview of Catiolanze and why it is authorised in the EU

What is Catiolanze and what is it used for?

Catiolanze is an eye drop medicine that is used to reduce intraocular pressure (pressure inside the eye) in adults who have open-angle glaucoma (a disease where the pressure in the eye rises because fluid cannot drain out of the eye) or ocular hypertension (when the pressure in the eye is higher than normal). It can also be used in children from 4 years of age and adolescents who have increased intraocular pressure or childhood glaucoma.

Catiolanze is a 'hybrid medicine'. This means that it is similar to a 'reference medicine' containing the same active substance, but there are certain differences between the two. In the case of Catiolanze, it has been formulated in a different way to its reference medicine, Xalatan. While Xalatan is available as an eye drop solution, Catiolanze is available as an eye drop emulsion (a mixture of oil- and water-based liquids).

Catiolanze contains the active substance latanoprost.

How is Catiolanze used?

The medicine can only be obtained with a prescription. It is available as an emulsion to be used as an eye drop once a day in the in the affected eye(s).

For more information about using Catiolanze, see the package leaflet or contact your doctor or pharmacist.

How does Catiolanze work?

When pressure in the eye increases, it can cause damage to the retina (the light-sensitive membrane at the back of the eye) and to the optic nerve that sends signals from the eye to the brain. This can result in serious vision loss and even blindness.

The active substance in Catiolanze, latanoprost, is a prostaglandin analogue (a man-made version of a prostaglandin, substances naturally found in the body). In the eye, prostaglandins increase the drainage of the watery fluid (aqueous humour) out of the eyeball. Catiolanze acts in the same way and increases the flow of fluid out of the eye. This helps to reduce the pressure inside the eye and reduces the risk of damage to the retina.

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What benefits of Catiolanze have been shown in studies?

A main study involving 386 adults with open angle glaucoma or ocular hypertension showed that Catiolanze was as effective as Xalatan at reducing pressure in the eye. After 3 months, treatment with Catiolanze reduced the eye pressure by around 8.6 to 8.8 mmHg, compared with reductions of 8.1 to 8.2 mmHg for patients treated with Xalatan.

Studies on the benefits and risks of the use of latanoprost in children have already been carried out with the reference medicine, Xalatan. Other medicines formulated as emulsion to be given into the eye have also been studied in children from 4 years of age and have been shown to be well-tolerated by this age group. It is therefore considered that data from adults apply to children from 4 years and adolescents as well.

What are the risks associated with Catiolanze?

For the full list of side effects and restrictions with Catiolanze, see the package leaflet.

The most common side effect with Catiolanze (which may affect more than 3 in 10 people) is iris hyperpigmentation (darkening of the colour of the iris).

Other common side effects with Catiolanze (which may affect up to 1 in 10 people) include ocular and conjunctival hyperaemia (redness of the eye).

Why is Catiolanze authorised in the EU?

Latanoprost has been shown to be effective in reducing intraocular pressure in adults and children. Based on studies involving adults with open angle glaucoma or ocular hypertension, Catiolanze is considered comparable to Xalatan in reducing intraocular pressure. In terms of safety, Catiolanze was shown to be well tolerated.

Therefore, the European Medicines Agency decided that Catiolanze's benefits are greater than its risks and it can be authorised for use in the EU.

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

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Catiolanze have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Catiolanze are continuously monitored. Suspected side effects reported with Catiolanze are carefully evaluated and any necessary action taken to protect patients.

Other information about Catiolanze

Catiolanze received a marketing authorisation valid throughout the EU on 15 November 2023.

Further information on Catiolanze can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/catiolanze.

This overview was last updated in 11-2023.