14 September 2023
EMA/CHMP/402547/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Catiolanze

latanoprost

On 14 September 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Catiolanze, intended for the reduction of elevated intraocular pressure (IOP) in adults with open angle glaucoma or ocular hypertension and in children from 4 years and adolescents with elevated IOP and paediatric glaucoma. The applicant for this medicinal product is Santen Oy.

Catiolanze will be available as a 50 µg/ml eye drop emulsion. The active substance of Catiolanze is latanoprost, a prostaglandin analogue (ATC code: S01EE01) that is believed to reduce IOP by increasing uveoscleral outflow.

Catiolanze is approved through a hybrid application[2] with Xalatan as the reference medicinal product which has been authorised in the EU since 1996. Catiolanze contains the same active substance as Xalatan, but is formulated in an emulsion formulation without benzalkonium chloride (BAK). Catiolanze contains the excipient cetalkonium chloride (CKC).

The benefit of Catiolanze is a reduction of IOP in line with that observed for its comparator Xalatan, as shown in a phase 3 randomised clinical trial. The most common side effects were ocular and conjunctival hyperaemia and abnormal sensation in the eye.

The full indication is:

> Catiolanze is indicated for the reduction of elevated intraocular pressure (IOP) in adult patients with open angle glaucoma or ocular hypertension.
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> Catiolanze is indicated for the reduction of elevated IOP in children from 4 years of age and adolescents with elevated IOP and paediatric glaucoma.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion
[2] Hybrid applications rely in part on the results of pre-clinical tests and clinical trials for a reference product and in part on new data.

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Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.