12 November 2020
EMA/CHMP/593876/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Roclanda

latanoprost / netarsudil

On 12 November 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Roclanda, intended for the reduction of elevated intraocular pressure (IOP) in adult patients with primary open-angle glaucoma or ocular hypertension for whom monotherapy with a prostaglandin or netarsudil provides insufficient IOP reduction. The applicant for this medicinal product is Aerie Pharmaceuticals Ireland Limited.

Roclanda will be available as 50 µg/ml /200 µg/ml Eye drops, solution. The active substances of Roclanda are latanoprost (a prostaglandin analogue) and netasurdil (a rho kinase inhibitor).

The benefit with Roclanda is its ability to reduce intra-ocular pressure. The most common side effects is conjunctival hyperemia.

The full indication is: "Roclanda is indicated for the reduction of elevated intraocular pressure (IOP) in adult patients with primary open-angle glaucoma or ocular hypertension for whom monotherapy with a prostaglandin or netarsudil provides insufficient IOP reduction".

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.

[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

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