EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 September 2019
EMA/505213/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Rhokiinsa

netarsudil

On 19 September 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Rhokiinsa, intended for the treatment of patients with glaucoma or ocular hypertension. The applicant for this medicinal product is Aerie Pharmaceuticals Ireland Ltd.

Rhokiinsa will be available as a 200 microgram/ml eye drop solution. The active substance of Rhokiinsa is netarsudil, a Rho kinase inhibitor that is thought to reduce intraocular pressure (IOP) by increasing outflow of aqueous humor through the trabecular outflow pathway and reducing episcleral venous pressure (ATC code: S01EX05).

The benefits with Rhokiinsa are its ability to reduce IOP. The most common side effect is conjunctival hyperaemia.

The full indication is: "Rhokiinsa is indicated for the reduction of elevated intraocular pressure (IOP) in adult patients with primary open-angle glaucoma or ocular hypertension". It is proposed that treatment with Rhokiinsa should only be initiated by an ophthalmologist or a healthcare professional qualified in ophthalmology.

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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