



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 May 2014
EMA/CHMP/276487/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Simbrinza

Brinzolamide/brimonidine tartrate

On 22 May 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Simbrinza, 10 mg/ml / 2 mg/ml, eye drops, suspension intended for the treatment of elevated intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension for whom monotherapy provides insufficient IOP reduction. The applicant for this medicinal product is Alcon Laboratories (UK) Ltd. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

Simbrinza contains two active substances: brinzolamide and brimonidine.

Brinzolamide belongs to the class of carbonic anhydrase inhibitors and reduces the ocular pressure by a direct antagonist activity on carbonic anhydrase within the ciliary epithelium, thereby decreasing the production of aqueous humor.

Brimonidine belongs to the class of alpha 2-adrenergic agonists and targets the alpha 2-receptor in the ciliary epithelium, ultimately resulting in suppression of aqueous humour formation.

The benefits with Simbrinza are its ability to lower the ocular pressure by means of the two different mechanisms of action described above. The most common side effects are ocular (topical) reactions. The most common were ocular hyperaemia, ocular discomfort, blurred vision, and ocular allergy.

A pharmacovigilance plan for Simbrinza will be implemented as part of the marketing authorisation.

The approved indication is: "Decrease of elevated intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension for whom monotherapy provides insufficient IOP reduction".

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.



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.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Simbrinza and therefore recommends the granting of the marketing authorisation.