27 March 2025
EMA/CHMP/103734/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Ryjunea

atropine sulfate

On 27 March 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Ryjunea, intended for slowing the progression of myopia in children aged 3 to 14 years.

The applicant for this medicinal product is Santen Oy.

Ryjunea will be available as a 0.1 mg/ml eye drop solution. The active substance of Ryjunea is atropine sulfate, an anticholinergic (ATC code: S01FA01). Atropine is a competitive antagonist which blocks muscarinic receptors from stimulation by acetylcholine. The mechanism by which atropine slows myopia progression is not fully understood, and it is thought to involve scleral remodelling and strengthening, resulting in reduced eye length and vitreous chamber depth.

The benefit of Ryjunea is its ability to reduce the mean annual progression rate of myopia compared with vehicle, as observed in a double masked vehicle-controlled phase 3 study in children aged 3 to 14 years. The most common side effects with Ryjunea include photophobia, eye irritation and blurred vision.

Ryjunea is a hybrid medicine[2] of Atropin-POS, which has been authorised in the EU since 25 April 2005. Ryjunea contains the same active substance as Atropin-POS, but is available at a lower strength and for a different indication.

The full indication of Ryjunea is:

> Ryjunea is indicated for slowing the progression of myopia in paediatric patients. Treatment may be initiated in children aged 3-14 years with a progression rate of 0.5 D or more per year and a severity of -0.5 D to -6.0 D.

Ryjunea 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

[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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characteristics (SmPC), which will be published on the EMA website in all official European Union languages after the marketing authorisation has been granted by the European Commission.