30 May 2024
EMA/248910/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Akantior

polihexanide

On 30 May 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Akantior[2], intended for the treatment of *Acanthamoeba* keratitis, a severe, progressive and sight threatening corneal infection characterized by intense pain and photophobia. *Acanthamoeba* keratitis is a rare disease primarily affecting contact lens wearers.

The applicant for this medicinal product is SIFI SPA.

Akantior will be available as 0.8 mg/ml eye drops solution. The active substance of Akantior is polihexanide, an anti-infective for ophthalmological use (ATC code: S01AX24) with a mechanism of action that involves both disruption of *Acanthamoeba* cell membranes and damage to *Acanthamoeba*'s chromosomes.

The benefit of Akantior is a higher clinical resolution rate (defined as no corneal inflammation requiring treatment, no or mild conjunctival inflammation, no limbitis, scleritis or anterior chamber inflammation, and no relapse within 30 days of discontinuing all topical therapy) compared to historical data in patients who were not given anti-amoebal treatment. The most common side effects with Akantior are eye pain and ocular hyperaemia.

The full indication is:

> Akantior is indicated for the treatment of *Acanthamoeba* keratitis in adults and children from 12 years of age.

Akantior should be prescribed by physicians experienced in the diagnosis and treatment of *Acanthamoeba* keratitis.

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

[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] This product was designated as an orphan medicine during its development. EMA will now review the information available to date to determine if the orphan designation can be maintained

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made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.