20 July 2017
EMA/CHMP/372110/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Verkazia

ciclosporin

On 20 July 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Verkazia, intended for the treatment of severe vernal keratoconjunctivitis. Verkazia, which was designated as an orphan medicinal product on 6 April 2006, was reviewed under EMA's accelerated assessment programme. The applicant for this medicinal product is Santen Oy.

Verkazia will be available as 1 mg/ml eye drops. The active substance of Verkazia is ciclosporin, an immunosuppressant (ATC code: S01XA18) which blocks the release of pro-inflammatory cytokines and exerts an anti-inflammatory effect.

The benefits of Verkazia are its ability to improve ocular surface damage and reduce symptoms of severe vernal keratoconjunctivitis in children and adolescent patients. The most common side effects are eye pain (11%) and eye pruritus (9%) which usually occur at the time of instilling the eye drops.

The full indication is: "Treatment of severe vernal keratoconjunctivitis in children from 4 years of age and adolescents". Treatment with Verkazia must 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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