25 July 2024
EMA/CHMP/320011/2024
Committee for Medicinal Products for Human Use (CHMP)

**Summary of opinion[1] (initial authorisation)**

# Vevizye

ciclosporin

On 25 July 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 Vevizye, intended for the treatment of dry eye disease.

The applicant for this medicinal product is Novaliq GmbH.

Vevizye will be available as 1 mg/ml eye drops solution. The active substance of Vevizye is ciclosporin, an ophthalmological (ATC code: S01XA18) which has anti-inflammatory and immunosuppressive properties.

in a main study, the benefit of Vevizye was a reduction in corneal surface damage in patients with dry eye disease, as evidenced by an improvement in the total corneal fluorescein staining score compared to the placebo group. The most common side effects with Vevizye are instillation site reactions and blurred vision.

The full indication is:

> Treatment of moderate to severe dry eye disease (keratoconjuctivitis sicca) in adult patients, which has not improved despite treatment with tear substitutes (see section 5.1).

Treatment with Vevizye should be prescribed and supervised by an ophthalmologist.

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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