



22 January 2015
EMA/CHMP/14288/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

IKERVIS ciclosporin

On 22 January 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product IKERVIS, 1 mg/ml, eye drops intended for the treatment of severe keratitis in adult patients with dry eye disease (DED). The applicant for this medicinal product is Santen SAS. 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.

The active substance of IKERVIS is ciclosporin, an immunosuppressant belonging to the therapeutic class of ophthalmologicals (S01XA18). Ciclosporin blocks the release of pro-inflammatory cytokines and exerts an anti-inflammatory effect in ocular surface cells.

The benefits with IKERVIS are its ability to improve ocular surface damage and reduce inflammation in DED patients with severe keratitis, which is thought to help prevent disease progression and worsening. The most common side effects are eye pain (19%), eye irritation (17.8%), lacrimation (6.2%), ocular hyperaemia (5.5%) and eyelid erythema (1.7%).

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

The approved indication is: "Treatment of severe keratitis in adult patients with dry eye disease, which has not improved despite treatment with tear substitutes (see section 5.1)".

Ikervis treatment 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.



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