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

# Oxervate

cenegermin

On 18 May 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 Oxervate, intended for the treatment of moderate to severe neurotrophic keratitis. Oxervate, which was designated as an orphan medicinal product on 14 December 2015, was reviewed under EMA's accelerated assessment programme. The applicant for this medicinal product is Dompé farmaceutici S.p.A.

Oxervate will be available as a 20 microgram/ml eye drops solution. The active substance of Oxervate is cenegermin, a recombinant form of human nerve growth factor, which exerts a trophic effect and induces corneal epithelial cell growth and survival.

The benefits with Oxervate are its ability to stimulate corneal healing and restore ocular surface integrity in patients with neurotrophic keratitis suffering from persistent epithelial defects or corneal ulcers. The most common side effects are eye pain, eye inflammation, increased lacrimation and foreign body sensation in the eye.

The full indication is: "Treatment of moderate (persistent epithelial defect) or severe (corneal ulcer) neurotrophic keratitis in adults". It is proposed that Oxervate treatment be initiated and supervised 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.

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[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

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
**Telephone** +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
**Send a question via our website** www.ema.europa.eu/contact

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