13 October 2016
EMA/CHMP/643776/2016
Committee for Medicinal Products for Human Use (CHMP)

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

# Cystadrops

## mercaptamine

On 13 October 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Cystadrops, intended for the treatment of corneal cystine crystal deposits in patients with cystinosis. Cystadrops was designated as an orphan medicinal product on 7 November 2008. The applicant for this medicinal product is Orphan Europe S.A.R.L.

Cystadrops will be available as a 3.8 mg/g eye-drop solution. The active substance of Cystadrops is mercaptamine, a cystine-depleting agent (ATC code: S01XA21) which works by converting cystine to cysteine and cysteine-cysteamine mixed disulfides.

The benefit of Cystadrops is its ability to reduce corneal cystine crystal accumulation. The most common side effects are eye pain, ocular hyperaemia, eye pruritus, increased lacrimation, blurred vision and eye irritation.

The full indication is: "Cystadrops is indicated for the treatment of corneal cystine crystal deposits in adults and children from 2 years of age with cystinosis." It is proposed that Cystadrops be prescribed by physicians experienced in the management of cystinosis.

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

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