European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

London, 29 May 2009
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
VEDROP

International Nonproprietary Name (INN): ***tocofersolan***

On 29 May 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending to grant a marketing authorisation under exceptional circumstances for the medicinal product Vedrop, 50 mg/ml, oral solution indicated in vitamin E deficiency due to digestive malabsorption in paediatric patients suffering from congenital chronic cholestasis or hereditary chronic cholestasis.
The applicant for this medicinal product is Orphan Europe S.A.R.L.

The active substance of Vedrop is tocofersolan, an alimentary tract and metabolism medicinal product (ATC code A11 HA08, other plain vitamin preparations). Tocofersolan, is vitamin E that has been made water-soluble by attaching it to polyethylene glycol 1000, and thereby can be absorbed from the gut in patients who have difficulty absorbing fats and vitamin E from the diet due congenital chronic or hereditary chronic cholestasis. The use of vitamin E preparations in this population helps to prevent neurological deterioration due to vitamin E deficiency.

The benefits with Vedrop are improvement or stabilisation of neurological abnormalities due to vitamin E deficiency in patients with congenital chronic or hereditary chronic cholestasis. The most common side effect is diarrhoea.

A pharmacovigilance plan for Vedrop, as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication is: "Vedrop is indicated in vitamin E deficiency due to digestive malabsorption in paediatric patients suffering from congenital chronic cholestasis or hereditary chronic cholestasis, from birth (in term newborns) to 16 or 18 years of age, depending on the region".
It is proposed that the treatment with Vedrop should be initiated and supervised by a physician experienced in the management of patients suffering from congenital chronic cholestasis or hereditary chronic cholestasis.

Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Vedrop and therefore recommends the granting of the marketing authorisation under exceptional circumstances**.

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* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

** Marketing Authorisation under exceptional circumstances refers to the fact that in exceptional circumstances an authorisation may be granted subject to certain specific obligations, to be reviewed annually.

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 8613
E-mail: mail@emea.europa.eu http://www.emea.europa.eu