20 February 2014
EMA/CHMP/95120/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Hemangiol

propranolol

On 20 February 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Hemangiol, 3.75mg/ml, oral solution intended for the treatment of proliferating infantile haemangioma requiring systemic therapy.

The applicant for this medicinal product is PIERRE FABRE DERMATOLOGIE. 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 Hemangiol is propranolol, a beta-blocking agent (C07AA05). Potential mechanisms of action of propranolol in proliferating infantile haemangioma described in the literature could include various mechanisms all in close relationship (a local haemodynamic effect, an antiangiogenic effect, an apoptosis-triggering effect on capillary endothelial cells or a reduction of both VEGF and bFGF signalling pathways).

The benefits with Hemangiol are its ability to result in a complete or nearly complete resolution of the target haemangioma, which was evaluated by blinded centralised independent assessments made on photographs at Week 24. The most common side effects are sleep disorders, aggravated respiratory tract infections such as bronchitis and bronchiolitis associated with cough and fever, diarrhoea, and vomiting.

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

The approved indication is: "HEMANGIOL is indicated in the treatment of proliferating infantile haemangioma requiring systemic therapy:

- Life- or function-threatening haemangioma,
- Ulcerated haemangioma with pain and/or lack of response to simple wound care measures,
- Haemangioma with a risk of permanent scars or disfigurement.

[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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It is to be initiated in infants aged 5 weeks to 5 months (see sections 4.2 and 4.4)"".

It is proposed that Hemangiol be prescribed by physicians who have expertise in the diagnosis, treatment and management of infantile haemangioma.

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.

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