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EPAR summary for the public

Hemangiol

propranolol

This is a summary of the European public assessment report (EPAR) for Hemangiol. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Hemangiol.

For practical information about using Hemangiol, patients should read the package leaflet or contact their doctor or pharmacist.

What is Hemangiol and what is it used for?

Hemangiol is a medicine that contains the active substance propranolol. It is used to treat children with proliferating infantile haemangioma, which are benign tumours (abnormal non-cancerous growths) of blood vessels.

Hemangiol is used in infants with serious complications, such as painful ulcers, scarring and breathing difficulties, who require systemic therapy (treatment which can have an effect on the whole body).

Treatment with Hemangiol is started in babies aged five weeks to five months.

How is Hemangiol used?

Hemangiol can only be obtained with a prescription. Treatment should be started by a doctor who has experience in the diagnosis, treatment and management of infantile haemangioma. Treatment should be started in appropriate facilities in case serious side effects develop.

Hemangiol is available as a solution to be taken by mouth. The recommended starting dose of Hemangiol is 0.5 mg per kilogram bodyweight (0.5 mg/kg), twice a day (at least 9 hours apart). The dose is progressively increased to a maintenance dose of 1.5 mg/kg twice a day. The dose is given to the baby during or immediately after a feed using the oral syringe provided. Treatment with Hemangiol should last for six months and the child should be monitored once a month, in particular for dose adjustments. For further information, see the package leaflet.

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How does Hemangiol work?

The active substance in Hemangiol, propranolol, belongs to a group of medicines called beta-blockers, which have been widely used to treat several conditions in adults, including diseases of the heart and high blood pressure.

Although it is not exactly known how Hemangiol works in proliferative infantile haemangioma, it is thought to do so by several mechanisms including narrowing the blood vessels and so decreasing blood supply to the haemangioma, blocking the formation of new blood vessels in the growth, triggering cell death of the abnormal blood vessel cells and blocking the effect of certain proteins (called VEGF and bFGF), which are important for the growth of blood vessels.

What benefits of Hemangiol have been shown in studies?

Hemangiol was investigated in one main study involving 460 children aged from five weeks to five months at the start of treatment and who had proliferative infantile haemangioma that required systemic therapy. The study compared different doses of propranolol with placebo (a dummy treatment) and the main measure of effectiveness was based on whether the haemangiomas disappeared completely or almost completely after 6 months of treatment.

Hemangiol at a dose of 3 mg/kg per day (given as two separate doses of 1.5 mg/kg) given for 6 months was shown to be more effective than placebo. In around 60% (61 out of 101) of children treated with the most effective dose of Hemangiol (3 mg/kg/day for 6 months), haemangiomas disappeared completely or almost completely compared with around 4% (2 out of 55) in children who received placebo.

What are the risks associated with Hemangiol?

The most common side effects with Hemangiol (which may affect more than 1 in 10 children) are sleep disorders, respiratory tract infections such as bronchitis (inflammation of the airways in the lungs), diarrhoea and vomiting. Serious side effects observed with Hemangiol include bronchospasm (temporary narrowing of the airways) and low blood pressure. For the full list of all side effects reported with Hemangiol, see the package leaflet.

Hemangiol must not be used in: premature babies who have not reached the corrected age of 5 weeks (the corrected age is the age a premature baby would be if he/she had been born on the due date); breastfed children if the mother is being treated with medicines that must not be used with propranolol; children with asthma or with a history of bronchospasm; children with certain diseases of the heart and blood vessels, such as low blood pressure; and children who tend to have low blood sugar levels. For the full list of restrictions, see the package leaflet.

Why is Hemangiol approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Hemangiol's benefits are greater than its risks and recommended that it be approved for use in the EU. The Committee concluded that Hemangiol was an effective treatment for haemangioma. Regarding safety, the CHMP considered that the safety profile is acceptable; the risks identified are those already known for propranolol and can be appropriately managed.

What measures are being taken to ensure the safe and effective use of Hemangiol?

A risk management plan has been developed to ensure that Hemangiol is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Hemangiol, including the appropriate precautions to be followed by healthcare professionals and patients.

The Company will provide caregivers who will give Hemangiol to children with an educational pack to inform them of the need to monitor children for certain side effects and how to manage them. It will also provide instructions on how to give the medicine correctly, in order to avoid the risk of low blood sugar levels.

Further information can be found in the summary of the risk management plan.

Other information about Hemangiol

The European Commission granted a marketing authorisation valid throughout the European Union for Hemangiol on 23 April 2014.

The full EPAR and risk management plan summary for Hemangiol can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Hemangiol, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 04-2014.