19 November 2015
EMA/CHMP/730109/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Spectrila

asparaginase

On 19 November 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Spectrila, intended for the treatment of acute lymphoblastic leukaemia. Spectrila was designated as an orphan medicinal product on 26 January 2005. The applicant for this medicinal product is medac Gesellschaft fuer klinische Spezialpraeparate mbH.

Spectrila will be available as a 10,000 U powder for concentrate for solution for infusion. The active substance of Spectrila is asparaginase, an antineoplastic agent (ATC code: L01XX02). The mechanism of action of asparaginase is the enzymatic degradation of the amino acid asparagine. Depletion of asparagine in blood serum results in apoptosis of cells highly dependent on asparagine, especially leukaemic blasts.

Consequent to the complete asparagine depletion in serum, the benefit with Spectrila administered as part of combination chemotherapy is to increase the proportion of patients with complete remission at the end of the treatment period.

The most common side effects are hypersensitivity reactions, hyperglycaemia, hypoalbuminaemia, nausea, vomiting, diarrhoea, abdominal pain, oedema, fatigue, and change in laboratory parameters (e.g. transaminases, bilirubin, blood lipids and coagulation parameters).

The full indication is: "Spectrila is indicated as a component of antineoplastic combination therapy for the treatment of acute lymphoblastic leukaemia (ALL) in paediatric patients from birth to 18 years and adult patients". It is proposed that Spectrila be prescribed and administered by physicians and healthcare personnel experienced in the use of antineoplastic products.

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

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