19 November 2015
EMA/CHMP/734982/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Oncaspar

pegaspargase

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 Oncaspar, intended for the treatment of acute lymphoblastic leukaemia. The applicant for this medicinal product is Baxalta Innovations GmbH. In Europe, Oncaspar was authorised in 1994 in Germany and in 2008 in Poland for the treatment of patients with acute lymphoblastic leukaemia who were hypersensitive to native forms of asparaginase.

Oncaspar will be available as a 750 U/ml solution for injection or infusion. The active substance of Oncaspar is pegaspargase, an antineoplastic agent (ATC code: L01XX24). Pegaspargase is obtained by PEGylation of the asparaginase enzyme. 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.
The PEGylation does not change the enzymatic properties of asparaginase, but it prolongs the half-life of asparaginase and reduces its immunogenicity.

Consequent to the complete asparagine depletion in serum, the benefit with Oncaspar administered as part of combination chemotherapy is its ability to increase the proportion of patients who have complete remission at the end of the treatment period. Oncaspar has shown to be effective when administered to patients non-hypersensitive to native forms of asparaginase as well as patients previously treated and hypersensitive to native forms of asparaginase.

The most common side effects are hypersensitivity including anaphylactic reaction, febrile neutropenia, anaemia, hyperglycaemia, decreased platelet count, decreased neutrophil count and increased blood bilirubin.

The full indication is: "Oncaspar is indicated as a component of antineoplastic combination therapy in acute lymphoblastic leukaemia (ALL) in paediatric patients from birth to 18 years, and adult patients". It is proposed that Oncaspar be prescribed and administered by physicians and

[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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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.