20 July 2023
EMA/323951/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Enrylaze

crisantaspase

On 20 July 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Enrylaze, intended for the treatment of acute lymphoblastic leukaemia (ALL) and lymphoblastic lymphoma (LBL). The applicant for this medicinal product is Jazz Pharmaceuticals Ireland Limited.

Enrylaze will be available as a 10 mg/ 0.5 ml solution for injection/infusion. The active substance of Enrylaze is crisantaspase, an antineoplastic agent (ATC code: L01XX02). Crisantaspase catalyses the conversion of L-asparagine into L-aspartic acid and ammonia. Depletion of asparagine in blood serum results in apoptosis of cells highly dependent on asparagine, especially leukaemic blasts.

The benefit of Enrylaze is the achievement and maintenance of nadir (minimal) serum asparaginase activity, which has been demonstrated to correlate with serum asparagine depletion. The most common side effects are anaemia, vomiting, thrombocytopenia, neutropenia, nausea, febrile neutropenia, fatigue and pyrexia.

The full indication is:

> Enrylaze is indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of acute lymphoblastic leukaemia (ALL) and lymphoblastic lymphoma (LBL) in adult and paediatric patients (1 month and older) who developed hypersensitivity or silent inactivation to E. coli-derived asparaginase.

Enrylaze should 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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