12 December 2024
EMA/557861/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Zefylti

filgrastim

On 12 December 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Zefylti, intended for the treatment of neutropenia and the mobilisation of peripheral blood progenitor cells (PBPCs).

The applicant for this medicinal product is CuraTeQ Biologics s.r.o.

Zefylti will be available as 30 MU/0.5 ml and 48 MU/0.5 ml solution for injection or infusion in pre-filled syringe. The active substance of Zefylti is filgrastim, an immunostimulant, colony stimulating factor (ATC code: L03AA02). Filgrastim is a recombinant granulocyte colony-stimulating factor (G-CSF), a type of haematopoietic growth factor. By binding to the G-CSF receptor, filgrastim stimulates the production and differentiation of mature and functionally active neutrophils from bone marrow precursor cells.

Zefylti is a biosimilar medicinal product. It is highly similar to the reference product Neupogen (filgrastim), which has been authorised in various EU countries. Data show that Zefylti has comparable quality, safety and efficacy to Neupogen (filgrastim). More information on biosimilar medicines can be found here.

The full indication is:

> Zefylti is indicated for the reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with established cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes) and for the reduction in the duration of neutropenia in patients undergoing myeloablative therapy followed by bone marrow transplantation considered to be at increased risk of prolonged severe neutropenia.
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> The safety and efficacy of Zefylti are similar in adults and children receiving cytotoxic chemotherapy.

[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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Zefylti is indicated for the mobilisation of peripheral blood progenitor cells (PBPCs).

In patients, children or adults, with severe congenital, cyclic, or idiopathic neutropenia with an absolute neutrophil count (ANC) of ≤ 0.5 x 10^9/L, and a history of severe or recurrent infections, long term administration of Zefylti is indicated to increase neutrophil counts and to reduce the incidence and duration of infection-related events.

Zefylti is indicated for the treatment of persistent neutropenia (ANC less than or equal to 1.0 x 10^9/L) in patients with advanced HIV infection, in order to reduce the risk of bacterial infections when other options to manage neutropenia are inappropriate.

Zefylti should be prescribed and given by physicians experienced in oncology and haematology.

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.