19 June 2025
EMA/210820/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Vivlipeg

pegfilgrastim

On 19 June 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Vivlipeg, intended to reduce the duration of neutropenia and the incidence of febrile neutropenia after cytotoxic chemotherapy. The applicant for this medicinal product is Biosimilar Collaborations Ireland Limited.

Vivlipeg will be available as a 6 mg solution for injection in pre-filled syringes. The active substance of Vivlipeg is pegfilgrastim, an immunostimulant, colony-stimulating factor (ATC code: L03AA13) which stimulates the development and differentiation of mature and functionally active neutrophils from precursor cells in the bone marrow.

Vivlipeg is a biosimilar medicinal product. It is highly similar to the reference product Neulasta (pegfilgrastim), which was authorised in the EU on 22 August 2002. Data show that Vivlipeg has comparable quality, safety and efficacy to Neulasta (pegfilgrastim). More information on biosimilar medicines can be found here.

The full indication is:

> Reduction in the duration of neutropenia and the incidence of febrile neutropenia in adult patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes).

Vivlipeg should be initiated and supervised by physicians experienced in oncology and/or haematology.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website 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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