



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Grasustek pegfilgrastim

On 26 April 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Grasustek, intended for prophylaxis against neutropenia in adult patients treated with cytotoxic chemotherapy. The applicant for this medicinal product is Juta Pharma GmbH.

Grasustek will be available as a 6 mg solution for injection. The active substance of Grasustek is pegfilgrastim, an immunostimulant and colony stimulating factor (ATC Code: L03AA13), which regulates the production and release of neutrophils from the bone marrow.

Grasustek 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 Grasustek has comparable quality, safety and efficacy to Neulasta. 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)." It is proposed that Grasustek be prescribed 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 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

