26 July 2018
EMA/490650/2018
Committee for Medicinal Products for Human Use (CHMP)

**Summary of opinion[1] (initial authorisation)**

# Udenyca

## pegfilgrastim

On 26 July 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Udenyca, intended to reduce the duration of neutropenia and the incidence of febrile neutropenia due to chemotherapy. The applicant for this medicinal product is ERA Consulting GmbH.

Udenyca will be available as a 6-mg solution for injection. The active substance of Udenyca is pegfilgrastim, an immunostimulant (ATC code: L03AA13) that belongs to the class of haematopoietic growth factors (granulocyte-colony stimulating factor; G-CSF) which increase the production and differentiation of mature and functionally active neutrophils from bone marrow precursor cells.

Udenyca 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 Udenyca 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 Udenyca 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 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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