



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 July 2026
EMADOC-1829012207-59658
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Cavoley pegfilgrastim

On 23 July 2026, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Cavoley, intended to reduce the duration of neutropenia and the incidence of febrile neutropenia after cytotoxic chemotherapy.

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

Cavoley will be available as 6 mg solution for injection in pre-filled syringes. The active substance of Cavoley 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.

Cavoley 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 Cavoley 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).

Cavoley 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

