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Public statement

Udenyca

Withdrawal of the marketing authorisation in the European Union

On 4 February 2021, the European Commission withdrew the marketing authorisation for Udenyca (pegfilgrastim) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, ERA Consulting GmbH, which notified the European Commission of its decision not to market the product in the EU for commercial reasons.

Udenyca was granted marketing authorisation in the EU on 21 September 2018 for treatment of neutropenia. The marketing authorisation was initially valid for a 5-year period.

Udenyca is a biosimilar of Neulasta, which is authorised in the EU to treat neutropenia.

The European Public Assessment Report (EPAR) for Udenyca will be updated to indicate that the marketing authorisation is no longer valid.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union