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Public statement

Biograstim

Withdrawal of the marketing authorisation in the European Union

On 23 September 2015, the European Commission withdrew the marketing authorisation for Biograstim (filgrastim) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, AbZ Pharma GmbH, who notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Biograstim was granted marketing authorisation in the EU on 15 September 2008 for treatment of neutropenia. The marketing authorisation was initially valid for a 5-year period. It was then granted unlimited validity.

Biograstim is a biosimilar medicine of the reference medicinal product Neupogen and Biograstim was authorised in the EU for reducing the duration of neutropenia and the incidence of febrile neutropenia in patients treated with established cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes) and for reducing the duration of neutropenia in patients undergoing myeloablative therapy followed by bone marrow transplantation who were considered to be at increased risk of prolonged severe neutropenia.

Additional indications of Biograstim include mobilising peripheral blood progenitor cells (PBPC) in graft donors, increasing neutrophil counts and reducing the incidence and duration of infection-related events in patients with severe congenital, cyclic, or idiopathic neutropenia, and treating persistent neutropenia in patients with advanced HIV infection.

The European public assessment report (EPAR) for Biograstim will be updated to indicate that the marketing authorisation is no longer valid.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact