18 March2010
EMA/CHMP/117846/2010
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

NIVESTIM

filgrastim

On 18 March 2010 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Nivestim, 12 MU/0.2 ml, 30 MU/0.5 ml, 48 MU/0.5 ml, solution for injection or infusion intended for the treatment of neutropenia. The applicant for this medicinal product is Hospira UK Ltd. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Nivestim is filgrastim, an immunostimulating medicinal product (L03AA02) which regulates the production and release of functional neutrophils from the bone marrow.

Nivestim is a biological medicinal product similar to the reference product Neupogen authorised in the EU. Studies have shown Nivestim to have a comparable quality, safety and efficacy profile to Neupogen (filgrastim).

The most common side effects are bone, joint and muscle pain, elevations in blood levels of uric acid and certain enzymes, leucocytosis, thrombocytopenia, anaemia, headache, nose bleed, enlarged spleen and nausea.

A pharmacovigilance plan for Nivestim will be implemented as part of the marketing authorisation.

The approved indication is:

> Filgrastim is indicated for the reduction in 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 the reduction in the duration of neutropenia in patients undergoing myeloablative therapy followed by bone marrow transplantation considered to be at increased risk of prolonged severe neutropenia.

[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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The safety and efficacy of filgrastim are similar in adults and children receiving cytotoxic chemotherapy.

Filgrastim is indicated for the mobilisation of peripheral blood progenitor cells (PBPC).

In patients, children or adults, with severe congenital, cyclic, or idiopathic neutropenia with an absolute neutrophil count (ANC) of $\leq 0.5 \times 10^9$ /l and a history of severe or recurrent infections, long term administration of filgrastim is indicated to increase neutrophil counts and to reduce the incidence and duration of infection-related events.

Filgrastim is indicated for the treatment of persistent neutropenia (ANC less than or equal to 1.0×10^9 /l in patients with advanced HIV infection, in order to reduce the risk of bacterial infections when other options to manage neutropenia are inappropriate.

Filgrastim therapy should only be given in collaboration with an oncology centre which has experience in granulocyte-colony stimulating factor (G-CSF) treatment and haematology and has the necessary diagnostic facilities. The mobilisation and apheresis procedures should be performed in collaboration with an oncology-haematology centre with acceptable experience in this field and where the monitoring of haematopoietic progenitor cells can be correctly performed.

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 will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit to risk balance for Nivestim and therefore recommends the granting of the marketing authorisation.