European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
FILGRASTIM RATIOPHARM

International Non-proprietary Name (INN): ***filgrastim***

On 24 July 2008, the Committee for Medicinal Products for Human Use (CHMP) adopted a revised positive opinion, recommending to grant a marketing authorisation for the medicinal product Filgrastim ratiopharm, solution for injection or infusion (30 MIU/0.5 ml and 48 MIU/0.8 ml) in a pre-filled syringe intended for the treatment of neutropenia. The Applicant for this medicinal product is ratiopharm GmbH.

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

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

The most common side effects are bone pain, diarrhoea, asthenia, myalgia, arthralgia, headache and pyrexia.

A pharmacovigilance plan for Filgrastim ratiopharm, as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indications are:

> Filgrastim ratiopharm 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. The safety and efficacy of filgrastim are similar in adults and children receiving cytotoxic chemotherapy.
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> Filgrastim ratiopharm is indicated for the mobilisation of peripheral blood progenitor cells (PBPC).
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> In patients, children or adults, with severe congenital, cyclic, or idiopathic neutropenia with an absolute neutrophil count (ANC) of 0.5 x 10^9/l, and a history of severe or recurrent infections, long term administration of Filgrastim ratiopharm is indicated to increase neutrophil counts and to reduce the incidence and duration of infection-related events.
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> Filgrastim ratiopharm is indicated for the treatment of persistent neutropenia (ANC less than or equal to 1.0 x 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.

* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

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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 aphaeresis 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 (SPC) 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 that there is a favourable benefit to risk balance for Filgrastim ratiopharm and therefore recommends the granting of the marketing authorisation.