European Medicines Agency

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EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

BIOGRASTIM

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.
If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Biograstim?

Biograstim is a solution for injection or for infusion (drip into a vein). It contains the active substance filgrastim.
Biograstim is a 'biosimilar' medicine. This means that Biograstim is similar to a biological medicine that is already authorised in the European Union (EU) and contains the same active substance (also known as the 'reference medicine'). The reference medicine for Biograstim is Neupogen. For more information on biosimilar medicines, see the question-and-answer document here.

What is Biograstim used for?

Biograstim is used to stimulate the production of white blood cells in the following situations:

- to reduce the duration of neutropenia (low levels of neutrophils, a type of white blood cell) and the occurrence of febrile neutropenia (neutropenia with fever) in patients receiving chemotherapy (cancer treatment) that is cytotoxic (cell-killing);
- to reduce the duration of neutropenia in patients undergoing treatment to destroy the bone marrow cells before a bone marrow transplant (such as in some patients with leukaemia) if they are at a risk of long-term, severe neutropenia;
- to increase levels of neutrophils and reduce the risk of infections in patients with neutropenia who have a history of severe, repeated infections;
- to treat persistent neutropenia in patients with advanced human immunodeficiency virus (HIV) infection, to reduce the risk of bacterial infections when other treatments are not appropriate.

Biograstim can also be used in patients who are about to donate blood stem cells for transplant, to help release these cells from the bone marrow.
The medicine can only be obtained with a prescription.

How is Biograstim used?

Biograstim is given by injection under the skin or infusion into a vein. How it is given, the dose and the duration of treatment depend on why it is being used, the patient's body weight and the response to treatment. Biograstim is usually given in a specialised treatment centre, although patients who receive it by injection under the skin may inject themselves once they have been trained appropriately. For more information, see the Package Leaflet.

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How does Biograstim work?
The active substance in Biograstim, filgrastim, is very similar to a human protein called granulocyte colony stimulating factor (G-CSF). Filgrastim is produced by a method known as 'recombinant DNA technology': it is made by a bacterium that has received a gene (DNA), which makes it able to produce filgrastim. The replacement acts in same way as naturally produced G-CSF by encouraging the bone marrow to produce more white blood cells.

How has Biograstim been studied?
Biograstim was studied to show that it is comparable to the reference medicine, Neupogen. Biograstim was compared to Neupogen and to placebo (a dummy treatment) in one main study involving 348 patients with breast cancer. The study looked at the duration of severe neutropenia during the patients' first cycle of cytotoxic chemotherapy.
To study the safety of Biograstim, two further studies were carried out in patients with lung cancer and with non-Hodgkin's lymphoma.

What benefit has Biograstim shown during the studies?
Treatment with Biograstim and Neupogen brought about similar reductions in duration of severe neutropenia. During the first 21-day chemotherapy cycle, patients treated with either Biograstim or Neupogen had severe neutropenia for an average of 1.1 days, compared with 3.8 days in those receiving placebo. Therefore, the effectiveness of Biograstim was shown to be equivalent to that of Neupogen.

What is the risk associated with Biograstim?
The most common side effect with Biograstim (seen in more than 1 patient in 10) is musculoskeletal pain (pain in the muscles and bones). Other side effects may be seen in more than 1 patient in 10, depending on the condition that Biograstim is being used for. For the full list of all side effects reported with Biograstim, see the Package Leaflet.
Biograstim should not be used in people who may be hypersensitive (allergic) to filgrastim or any of the other ingredients.

Why has Biograstim been approved?
The Committee for Medicinal Products for Human Use (CHMP) decided that, in accordance with EU requirements, Biograstim has been shown to have a comparable quality, safety and efficacy profile to Neupogen. Therefore, the CHMP's view was that, as for Neupogen, the benefit outweighs the identified risk. The Committee recommended that Biograstim be given marketing authorisation.

Other information about Biograstim:
The European Commission granted a marketing authorisation valid throughout the EU for Biograstim to CT Arzneimittel GmbH on 15 September 2008.

The full EPAR for Biograstim can be found here.

This summary was last updated in 09-2008.