EMA/434854/2014
EMEA/H/C/000918

EPAR summary for the public

Filgrastim Hexal

filgrastim

This is a summary of the European public assessment report (EPAR) for Filgrastim Hexal. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Filgrastim Hexal.

What is Filgrastim Hexal?

Filgrastim Hexal is a solution for injection or infusion (drip into a vein) in a pre-filled syringe. It contains the active substance filgrastim (30 or 48 million units).

Filgrastim Hexal is a 'biosimilar' medicine. This means that Filgrastim Hexal 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 Filgrastim Hexal is Neupogen. For more information on biosimilar medicines, see the question-and-answer document here.

What is Filgrastim Hexal used for?

Filgrastim Hexal 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;

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

- 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.

Filgrastim Hexal can also be used in people 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 Filgrastim Hexal used?

Filgrastim Hexal 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. Filgrastim Hexal 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.

How does Filgrastim Hexal work?

The active substance in Filgrastim Hexal, 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 bacteria into which a gene (DNA) has been introduced, which makes them able to produce filgrastim. The replacement acts in the same way as naturally produced G CSF by encouraging the bone marrow to produce more white blood cells.

How has Filgrastim Hexal been studied?

Filgrastim Hexal was studied to show that it is comparable to the reference medicine, Neupogen.

Four studies looked at the levels of neutrophils in the blood in a total of 146 healthy volunteers who received Filgrastim Hexal or Neupogen. The studies looked at the effects of single and repeated administration of various doses of the medicines, either injected under the skin or infused into a vein. The main measure in these studies was the neutrophil count over the first 10 days of treatment.

What benefit has Filgrastim Hexal shown during the studies?

Filgrastim Hexal and Neupogen brought about similar increases in blood neutrophil counts in healthy volunteers over the course of the studies. This was considered sufficient to demonstrate that the benefits of Filgrastim Hexal are comparable to those of the reference medicine.

What is the risk associated with Filgrastim Hexal?

The most common side effect with Filgrastim Hexal (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 Filgrastim Hexal is being used for. For the full list of all side effects and restrictions, see the package leaflet.

Why has Filgrastim Hexal been approved?

The CHMP decided that, in accordance with EU requirements, Filgrastim Hexal 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 Filgrastim Hexal be given marketing authorisation.

What measures are being taken to ensure the safe and effective use of Filgrastim Hexal?

A risk management plan has been developed to ensure that Filgrastim Hexal is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Filgrastim Hexal, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Filgrastim Hexal

The European Commission granted a marketing authorisation valid throughout the EU for Filgrastim Hexal on 06 February 2009.

The full EPAR for Filgrastim Hexal can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Filgrastim Hexal, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 07-2014.