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**EPAR summary for the public**

# Ratiograstim

filgrastim

This is a summary of the European public assessment report (EPAR) for Ratiograstim. 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 Ratiograstim.

## What is Ratiograstim?

Ratiograstim is a solution for injection or for infusion (drip into a vein). It contains the active substance filgrastim.

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

## What is Ratiograstim used for?

Ratiograstim 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;

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- 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.

Ratiograstim 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 Ratiograstim used?

Ratiograstim 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. Ratiograstim 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 Ratiograstim work?

The active substance in Ratiograstim, 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 same way as naturally produced G CSF by encouraging the bone marrow to produce more white blood cells.

## How has Ratiograstim been studied?

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

Ratiograstim was compared with Neupogen and with 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 Ratiograstim, two further studies were carried out in patients with lung cancer and with non-Hodgkin's lymphoma.

## What benefit has Ratiograstim shown during the studies?

Treatment with Ratiograstim and Neupogen brought about similar reductions in duration of severe neutropenia. During the first 21-day chemotherapy cycle, patients treated with either Ratiograstim 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 Ratiograstim was shown to be equivalent to that of Neupogen.

## What is the risk associated with Ratiograstim?

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

## Why has Ratiograstim been approved?

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

## What measures are being taken to ensure the safe and effective use of Ratiograstim?

A risk management plan has been developed to ensure that Ratiograstim 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 Ratiograstim, including the appropriate precautions to be followed by healthcare professionals and patients.

## Other information about Ratiograstim

The European Commission granted a marketing authorisation valid throughout the EU for Ratiograstim on 15 September 2008.

The full EPAR for Ratiograstim 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 Ratiograstim, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 07-2014.