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EPAR summary for the public

Accofil

filgrastim

This is a summary of the European public assessment report (EPAR) for Accofil. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Accofil.

For practical information about using Accofil, patients should read the package leaflet or contact their doctor or pharmacist.

What is Accofil and what is it used for?

Accofil is a medicine that 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 cytotoxic chemotherapy (medicines to treat cancer by killing cells);
- 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 risk of long-term, severe neutropenia;
- to help release cells from the bone marrow in patients who are about to donate blood stem cells for transplant;
- 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.

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Accofil, which contains the active substance filgrastim, is a 'biosimilar medicine'. This means that Accofil is similar to a biological medicine (also known as the 'reference medicine') that is already authorised in the European Union (EU). The reference medicine for Accofil is Neupogen. For more information on biosimilar medicines, see the question-and-answer document here.

How is Accofil used?

Accofil is available as a solution for injection or infusion (drip) in pre-filled syringes. It is given by injection under the skin or infusion into a vein. It can only be obtained with a prescription and treatment should be given in collaboration with a centre for cancer treatment.

The way Accofil is given, its dose and the duration of treatment depend on why it is being used, the patient's body weight and the response to treatment. More information can be found in the summary of product characteristics (also part of the EPAR).

How does Accofil work?

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

What benefits of Accofil have been shown in studies?

Studies were carried out to show that Accofil produces similar levels of the active substance in the body to Neupogen and increases the numbers of neutrophils in a comparable way.

Accofil was studied in one main study involving 120 female adult patients with breast cancer treated with chemotherapy known to cause neutropenia. Patients were given the chemotherapy on day 1 of a three-week cycle, and then received one dose of Accofil the next day and daily for up to 14 days. The main measure of effectiveness was the duration of severe neutropenia. Severe neutropenia lasted on average for 1.4 days. This is comparable with 1.6 days and 1.8 days reported in other studies found in the literature using filgrastim. Data from published studies indicate that the benefits and safety of filgrastim are similar in both adults and children receiving chemotherapy.

What are the risks associated with Accofil?

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

Why is Accofil approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that, in accordance with EU requirements for biosimilar medicines, Accofil 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 risks and recommended that it be approved for use in the EU.

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

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

Further information can be found in the summary of the risk management plan.

Other information about Accofil

The European Commission granted a marketing authorisation valid throughout the European Union for Accofil on 18 September 2014.

The full EPAR and risk management plan summary for Accofil 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 Accofil, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 09-2014.