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Grastofil (*filgrastim*)

An overview of Grastofil and why it is authorised in the EU

What is Grastofil and what is it used for?

Grastofil is a medicine that stimulates the production of white blood cells and is used:

- to reduce the duration of neutropenia (low levels of neutrophils, a type of white blood cell) and to prevent febrile neutropenia (neutropenia with fever) in cancer patients (excluding patients with chronic myeloid leukaemia or with myelodysplastic syndromes). Neutropenia is a common side effect of cancer treatment and can leave patients vulnerable to infections;
- 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.

Grastofil is a 'biosimilar medicine'. This means that Grastofil is highly similar to another biological medicine (the 'reference medicine') that is already authorised in the EU. The reference medicine for Grastofil is Neupogen. For more information on biosimilar medicines, see here.

How is Grastofil used?

Grastofil can only be obtained with a prescription and treatment should be given in collaboration with a centre for cancer treatment. The medicine is available in prefilled syringes and is given by injection under the skin or infusion (drip) into a vein.

The way Grastofil 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. For more information about using Grastofil, see the package leaflet or contact your doctor or pharmacist.

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How does Grastofil work?

The active substance in Grastofil, filgrastim, is very similar to a human protein called granulocyte colony stimulating factor (G-CSF). Filgrastim works in the same way as naturally produced G-CSF by encouraging the bone marrow to produce more white blood cells.

What benefits of Grastofil have been shown in studies?

Grastofil was studied in one main study involving 120 female adult patients with breast cancer treated with chemotherapy (medicines to treat cancer) known to cause neutropenia. Patients were given the chemotherapy on day 1 of a three-week cycle, and then received one dose of Grastofil 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 which compared with 1.6 days and 1.8 days reported in studies using filgrastim found in the literature. Data from published studies indicate that the benefits and safety of filgrastim are similar in both adults and children receiving chemotherapy.

Studies were also carried out to show that Grastofil produces levels of the active substance in the body that are comparable to the reference medicine, Neupogen.

What are the risks associated with Grastofil?

The most common side effects with Grastofil (which may affect more than 1 in 10 people) are fever, musculoskeletal pain (pain in the muscles and bones), anaemia (low red blood cell counts), vomiting and nausea (feeling sick). Other side effects may be seen in more than 1 patient in 10, depending on the condition that Grastofil is being used for. For the full list of side effects and restrictions with Grastofil, see the package leaflet.

Why is Grastofil approved?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Grastofil has been shown to have a comparable quality, safety and effectiveness to Neupogen. Therefore, the Agency's view was that, as for Neupogen, the benefits of Grastofil are greater than its risks and it can be authorised for use in the EU.

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

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Grastofil have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Grastofil are continuously monitored. Side effects reported with Grastofil are carefully evaluated and any necessary action taken to protect patients.

Other information about Grastofil

Grastofil received a marketing authorisation valid throughout the EU on 18 October 2013.

Further information on Grastofil can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports.

This overview was last updated in 09-2018.