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Zefylti (*filgrastim*)

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

What is Zefylti and what is it used for?

Zefylti 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 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.

Zefylti 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.

Zefylti contains the active substance filgrastim and is a biological medicine. It is a 'biosimilar medicine'; this means that Zefylti is highly similar to another biological medicine (the 'reference medicine') that is already authorised in the EU. The reference medicine for Zefylti is Neupogen. For more information on biosimilar medicines, see here.

How is Zefylti used?

Zefylti 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 pre-filled syringes and is given by injection under the skin or infusion (drip) into a vein.

The way Zefylti 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 Zefylti, see the package leaflet or contact your doctor or pharmacist.

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How does Zefylti work?

The active substance in Zefylti, 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 Zefylti have been shown in studies?

Laboratory studies comparing Zefylti with Neupogen have shown that the active substance in Zefylti is highly similar to that in Neupogen in terms of structure, purity and biological activity. Studies have also shown that giving Zefylti produces similar levels of the active substance in the body to those seen with Neupogen.

Because Zefylti is a biosimilar medicine, the studies on the effectiveness and safety of filgrastim carried out with Neupogen do not need to be repeated for Zefylti.

What are the risks associated with Zefylti?

The safety of Zefylti has been evaluated and, on the basis of all the studies carried out, the side effects of the medicine are considered to be comparable to those of the reference medicine Neupogen.

For the complete list of side effects and restrictions of Zefylti, see the package leaflet.

The most common side effects with Zefylti (which may affect more than 1 in 10 people) include fever, musculoskeletal pain (pain in the muscles and bones), anaemia (low levels of red blood cells), vomiting and nausea (feeling sick).

Why is Zefylti authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Zefylti has a highly similar structure, purity and biological activity to Neupogen and is distributed in the body in the same way.

The available data were considered sufficient to conclude that Zefylti will have the same effects as Neupogen in its authorised uses. Therefore, the Agency's view was that, as for Neupogen, the benefits of Zefylti outweigh the identified risks and it can be authorised for use in the EU.

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

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

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

Other information about Zefylti

Zefylti received a marketing authorisation valid throughout the EU on 12 February 2025.

Further information on Zefylti can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/zefylti.

This overview was last updated in 02-2025.