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Fulphila (*pegfilgrastim*)

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

What is Fulphila and what is it used for?

Fulphila is a medicine used in cancer patients to help with neutropenia (low levels of neutrophils, a type of white blood cell), which is a common side effect of cancer treatment and can leave patients vulnerable to infections.

It is given specifically to reduce the duration of neutropenia and prevent febrile neutropenia (when neutropenia is accompanied by fever).

Fulphila is not intended for use in patients with the blood cancer chronic myeloid leukaemia or with myelodysplastic syndromes (conditions in which large numbers of abnormal blood cells are produced, which can develop into leukaemia).

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

How is Fulphila used?

Fulphila can only be obtained with a prescription and treatment should be started and supervised by a doctor who has experience in the treatment of cancer or blood disorders. It is available as a prefilled syringe containing a solution for injection under the skin. Fulphila is given as a single dose of 6 mg injected under the skin at least 24 hours after the end of each cycle of chemotherapy (treatment with cancer medicines). Patients can inject themselves if they have been trained appropriately.

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

How does Fulphila work?

The active substance in Fulphila, pegfilgrastim, is a form of filgrastim, which is very similar to a human protein called granulocyte-colony-stimulating factor (G-CSF). Filgrastim works by encouraging the

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bone marrow to produce more white blood cells, increasing white blood cell counts and so treating neutropenia.

Filgrastim has been available in other medicines in the European Union (EU) for a number of years. In Fulphila, filgrastim has been 'pegylated' (attached to a chemical called polyethylene glycol). This slows down the removal of filgrastim from the body, allowing the medicine to be given less often.

What benefits of Fulphila have been shown in studies?

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

In addition, a study involving 194 patients who had chemotherapy before or after surgery for breast cancer showed that Fulphila was as effective as Neulasta in reducing the duration of neutropenia. Neutropenia lasted 1 day on average with both medicines.

Because Fulphila is a biosimilar medicine, the studies on effectiveness and safety of pegfilgrastim carried out with Neulasta do not all need to be repeated for Fulphila.

What are the risks associated with Fulphila?

The safety of Fulphila 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 Neulasta. The most common side effect with Fulphila (which may affect more than 1 in 10 people) is pain in the bones. Pain in muscles is also common. For the full list of side effects and restrictions with Fulphila, see the package leaflet.

Why is Fulphila authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Fulphila has a highly similar structure, purity and biological activity to Neulasta and is distributed in the body in the same way. In addition, studies in breast cancer patients undergoing chemotherapy have shown that the effectiveness of Fulphila is equivalent to that of Neulasta in reducing the duration of neutropenia.

All these data were considered sufficient to conclude that Fulphila will behave in the same way as Neulasta in terms of effectiveness and safety in its authorised uses. Therefore, the Agency's view was that, as for Neulasta, the benefit of Fulphila outweighs the identified risk and it can be authorised for use in the EU.

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

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

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

Other information about Fulphila

Fulphila received a marketing authorisation valid throughout the EU on 20 November 2018.

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

This overview was last updated in 11-2018.