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Stimufend (*pegfilgrastim*)

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

What is Stimufend and what is it used for?

Stimufend is a medicine used in patients with cancer 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 (neutropenia accompanied by fever).

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

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

Stimufend contains the active substance pegfilgrastim.

How is Stimufend used?

Stimufend 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. Stimufend 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 Stimufend, see the package leaflet or contact your doctor or pharmacist.

How does Stimufend work?

The active substance in Stimufend, 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

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

In Stimufend, as in the reference medicine, 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 Stimufend have been shown in studies?

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

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

What are the risks associated with Stimufend?

The safety of Stimufend 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 Stimufend (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 Stimufend, see the package leaflet.

Why is Stimufend authorised in the EU?

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

All these data were considered sufficient to conclude that Stimufend 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 benefits of Stimufend 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 Stimufend?

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

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

Other information about Stimufend

Stimufend received a marketing authorisation valid throughout the EU on 28 March 2022.

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

This overview was last updated in 03-2022.