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Nivestim (*filgrastim*)

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

What is Nivestim and what is it used for?

Nivestim 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.

Nivestim 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.

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

Nivestim contains the active substance filgrastim.

How is Nivestim used?

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

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How does Nivestim work?

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

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

In addition, a study in 279 female adult patients with breast cancer who were being treated with cancer medicines showed that Nivestim is comparable to the reference medicine, Neupogen. The main measure of effectiveness was the duration of severe neutropenia. The patients who received Nivestim had severe neutropenia for a similar length of time as the patients who received Neupogen.

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

What are the risks associated with Nivestim?

The safety of Nivestim 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.

The most common side effects with Nivestim (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 in 10 patients, depending on the condition that Nivestim is being used for. For the full list of side effects and restrictions with Nivestim, see the package leaflet.

Why is Nivestim approved?

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

All these data were considered sufficient to conclude that Nivestim will behave in the same way as Neupogen in terms of effectiveness and safety in its authorised uses. Therefore, the Agency's view was that, as for Neupogen, the benefits of Nivestim are greater than its risks and it can be authorised or use in the EU.

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

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

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

Other information about Nivestim

Nivestim received a marketing authorisation valid throughout the EU on 8 June 2010.

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

This overview was last updated in 08-2019.