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Nyvepria (*pegfilgrastim*)

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

What is Nyvepria and what is it used for?

Nyvepria 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 chemotherapy 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 due to an infection).

Nyvepria 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).

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

Nyvepria contains the active substance pegfilgrastim.

How is Nyvepria used?

Nyvepria 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. Nyvepria 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. Patients can inject themselves if they have been trained appropriately.

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

How does Nyvepria work?

The active substance in Nyvepria, 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.

Filgrastim has been available in other medicines in the EU for a number of years. In Nyvepria, 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 Nyvepria have been shown in studies?

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

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

What are the risks associated with Nyvepria?

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

Why is Nyvepria authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Nyvepria 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 Nyvepria 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 Nyvepria 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 Nyvepria?

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

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

Other information about Nyvepria

Nyvepria received a marketing authorisation valid throughout the EU on 18 November 2020.

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

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