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Nylaspeg (*pegfilgrastim*)

A plain-language overview of Nylaspeg and why it is authorised in the EU

What is Nylaspeg and what is it used for?

Nylaspeg 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 (neutropenia accompanied by fever).

Nylaspeg 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).

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

How is Nylaspeg used?

Nylaspeg 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. Nylaspeg is given as a single dose 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 Nylaspeg, see the package leaflet or contact your doctor or pharmacist.

How does Nylaspeg work?

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

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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 Nylaspeg, 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 Nylaspeg have been shown in studies?

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

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

Studies carried out with Nylaspeg are described in more detail in the medicine's assessment report.

What are the side effects and restrictions associated with Nylaspeg?

The safety of Nylaspeg has been evaluated and, based on all the studies carried out, the side effects of the medicine are considered to be comparable to those of Neulasta.

For the full list of side effects and restrictions with Nylaspeg, see the package leaflet.

The most common side effect with Nylaspeg (which may affect more than 1 in 10 people) is pain in the bones. Pain in muscles is also common and may affect up to 1 in 10 people.

Why is Nylaspeg authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Nylaspeg 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 Nylaspeg will have the same effects as Neulasta in its authorised uses.

Therefore, the Agency's view was that, as for Neulasta, the benefits of Nylaspeg 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 Nylaspeg?

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

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

Other information about Nylaspeg

Nylaspeg received a marketing authorisation valid throughout the EU on 20 August 2026.

Further information on Nylaspeg, including the package leaflet and assessment report, can be found on the Agency's website:https://www.ema.europa.eu/medicines/human/EPAR/nylaspeg.

For information about the availability of this medicine in your country, contact your national competent authority.