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Dyrupeg (*pegfilgrastim*)

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

What is Dyrupeg and what is it used for?

Dyrupeg 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) in patients treated with cytotoxic chemotherapy (a type of cancer treatment that kills cancer cells).

Dyrupeg 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).

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

How is Dyrupeg used?

Dyrupeg 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 and is given as a single injection 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 Dyrupeg, see the package leaflet or contact your doctor or pharmacist.

How does Dyrupeg work?

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

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

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

What are the risks associated with Dyrupeg?

The safety of Dyrupeg 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.

For the complete list of side effects and restrictions of Dyrupeg, see the package leaflet.

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

Why is Dyrupeg authorised in the EU?

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

The available data were considered sufficient to conclude that Dyrupeg will have the same effects as Neulasta in its authorised uses. Therefore, the Agency's view was that, as for Neulasta, the benefits of Dyrupeg 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 Dyrupeg?

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

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

Other information about Dyrupeg

Dyrupeg received a marketing authorisation valid throughout the EU on 28 March 2025.

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

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