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Neulasta (*pegfilgrastim*)

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

What is Neulasta and what is it used for?

Neulasta 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).

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

How is Neulasta used?

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

How does Neulasta work?

The active substance in Neulasta, 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 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 Neulasta, 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.

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What benefits of Neulasta have been shown in studies?

Neulasta has been studied in two main studies involving 467 patients with breast cancer who were being treated with chemotherapy. In both studies, the effectiveness of a single injection of Neulasta was compared with multiple daily injections of filgrastim during each of four chemotherapy cycles. The main measure of effectiveness was the duration of severe neutropenia during the first cycle of chemotherapy.

Neulasta was as effective as filgrastim in reducing the duration of severe neutropenia. In both studies, the patients had severe neutropenia for around 1.7 days during their first chemotherapy cycle. This compares with around five to seven days when no stimulating factor is used.

What are the risks associated with Neulasta?

The most common side effect with Neulasta (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 Neulasta, see the package leaflet.

Why has Neulasta been approved?

Neulasta is effective at reducing the duration of severe neutropenia during chemotherapy and its side effects were considered manageable. The European Medicines Agency decided that Neulasta's benefits are greater than its risks and it can be authorised for use in the EU.

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

The company that markets Neulasta will ensure that patients or carers using the medicine are provided with an alert card explaining how to use the injection device that delivers the medicine.

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

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

Other information about Neulasta

Neulasta received a marketing authorisation valid throughout the EU on 22 August 2002. Further information on Neulasta can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports.

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