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Vivlipeg (*pegfilgrastim*)

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

What is Vivlipeg and what is it used for?

Vivlipeg is a medicine used in adults 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. Vivlipeg is given specifically to reduce the duration of neutropenia and prevent febrile neutropenia (neutropenia accompanied by fever).

Vivlipeg 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).

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

How is Vivlipeg used?

Vivlipeg 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 pre-filled syringe containing a solution to be injected under the skin in the thigh, abdomen, belly or upper arm. A single injection is given 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 Vivlipeg, see the package leaflet or contact your doctor or pharmacist.

How does Vivlipeg work?

The active substance in Vivlipeg, 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 the bone marrow to produce more white blood cells, increasing white blood cell counts and so treating neutropenia. In Vivlipeg, filgrastim has been 'pegylated' (attached to a chemical called polyethylene

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glycol). This slows down the removal of filgrastim from the body, allowing the medicine to be given less often.

What benefits of Vivlipeg have been shown in studies?

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

In addition, a study involving 194 adults with breast cancer who were being treated with chemotherapy compared the effectiveness of Vivlipeg with that of Neulasta. Vivlipeg was as effective as Neulasta in reducing the duration of severe neutropenia to around 1 day.

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

What are the risks associated with Vivlipeg?

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

The safety of Vivlipeg 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 Neulasta.

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

Why has Vivlipeg been approved?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Vivlipeg has a highly similar structure, purity and biological activity to Neulasta and is distributed in the body in the same way. In addition, a study has shown that Vivlipeg and Neulasta are equivalent in terms of safety and effectiveness in adults with breast cancer being treated with chemotherapy.

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

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

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

Other information about Vivlipeg

Vivlipeg received a marketing authorisation valid throughout the EU on 18 August 2025.

Further information on Vivlipeg can be found on the Agency's website: https://www.ema.europa.eu/en/medicines/human/EPAR/vivlipeg.

This overview was last updated in 08-2025.