

Information for Patients about Medicines containing Lipegfilgrastim or Pegfilgrastim

March 2024

G-CSF (granulocyte-colony stimulating factor) is a type of protein called a growth factor. It helps the bone marrow to make more blood cells, and increases the number of some types of white blood cells in the body. It can be used with, or after, chemotherapy.

G-CSF is made naturally in the body, but it can also be made as a drug. Lipegfilgrastim and pegfilgrastim are biological medicines containing G-CSF. They are long-acting versions of G-CSF.

Lipegfilgrastim and pegfilgrastim are biological medicines that are often given with chemotherapy. Chemotherapy can reduce the number of white blood cells in your blood. These cells fight infection. If the number of white blood cells is low, you are more likely to get an infection. A low white blood cell count is sometimes called neutropenia.

The number of white blood cells usually goes back up naturally between the cycles of chemotherapy. Some people need lipegfilgrastim or pegfilgrastim to help increase their white blood cell count. This can reduce their risk of infection and mean that chemotherapy can be given on time and at the planned dose.

Your doctor has given you lipegfilgrastim or pegfilgrastim to encourage the part of your bone that makes blood cells to produce more white blood cells quickly.

What are the best-value biological medicines for long-acting G-CSFs?

The best-value biological medicines identified by the HSE for long-acting G-CSFs are:

- Lipegfilgrastim: **Lonquex®**
- Pegfilgrastim: **Neulasta®**, **Pelgraz®** and **Ziextenzo®**.

Pelgraz® and Ziextenzo® are biosimilar medicines; what is a biosimilar medicine?

A biosimilar medicine is very similar to the original biological medicine. It works in the same way.

Neulasta® was the original biological medicine for pegfilgrastim. When the patent for Neulasta® expired, biosimilar medicines containing pegfilgrastim became available. Pelgraz® and Ziextenzo® are biosimilar medicines of Neulasta®.

Are biosimilar medicines safe?

Biosimilar medicines are tested to show they are just as safe and effective as the original biological medicine.

What's changing?

From **April 2024**, we are changing the way medicines containing long-acting G-CSFs (i.e. pegfilgrastim and lipegfilgrastim) are prescribed under the HSE's High Tech Arrangement.

I am a new patient, what do the changes mean for me?

From **1 April 2024**, if you are starting treatment on a long-acting G-CSF, you will be prescribed and receive one of the best-value biological medicines:

- Lipegfilgrastim: **Lonquex®**
- Pegfilgrastim: **Neulasta®, Pelgraz®** and **Ziextenzo®**.

What's the definition of a new patient?

A new patient, is an adult, who has not been prescribed or received pegfilgrastim or lipegfilgrastim within the last six months.

I am an existing patient prescribed pegfilgrastim or lipegfilgrastim, what does the change mean for me?

If you are an existing patient, you will continue to receive your medicine from your community pharmacy. The changes outlined above do not apply to you.

Does my consultant know about these changes?

Yes. Consultants who care for patients with cancer are aware of these changes.

Why have the changes been introduced?

The best-value biological medicines are provided to the HSE at a lower cost. Prescribing the best-value biological medicines will save the HSE money. This means we can give new innovative medicines to even more patients, including for the treatment of cancer.

What supports are available?

Supports for patients prescribed this medicine include:

- nurse home visit to provide training on administering the injection
- supply of sharps bins and waste collection service
- provision of product information.

Your consultant or a member of their team will register you for these services.

Where can I get more information on biosimilar medicines?

Further information on biosimilar medicines and the best-value biological medicines is available on the following websites:

HSE-Medicines Management Programme: www.hse.ie/mmp under Best-value medicines

Health Products Regulatory Authority: www.hpra.ie/homepage/medicines/special-topics/biosimilar-medicines

European Medicines Agency: www.ema.europa.eu/en/human-regulatory/overview/biosimilar-medicines-overview#information-for-patients-and-healthcare-professionals-section