EMA/648074/2022
EMEA/H/C/002556

Lonquex (*lipegfilgrastim*)

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

What is Lonquex and what is it used for?

Lonquex is a medicine that contains the active substance lipegfilgrastim. It is used to reduce the duration of neutropenia (low levels of neutrophils, a type of white blood cell) and the occurrence of febrile neutropenia (neutropenia with fever) in patients with cancer aged 2 years and older receiving cytotoxic chemotherapy.

Cytotoxic chemotherapy (medicines that kill fast growing cells) commonly causes neutropenia because as well as killing cancer cells, it also kills other fast-growing cells such as neutrophils, leaving the patient at risk of infections.

Lonquex is not used in patients receiving chemotherapy for chronic myeloid leukaemia (a cancer of the white blood cells) and myelodysplastic syndromes (a disease that can develop into a leukaemia).

How is Lonquex used?

Lonquex is available as a solution for injection. It is given as an injection under the skin in the abdomen, upper arm or thigh. For adults and children weighing 45 kg or more, one 6-mg dose is given in each chemotherapy cycle around 24 hours after chemotherapy. For children weighing less than 45 kg, the dose is based on the child's weight.

The medicine can only be obtained with a prescription and treatment should be started and supervised by a doctor experienced in treating cancer and blood disorders. Patients or their carer may be able to inject the medicine themselves once they have been properly trained but the first injection should be given under the direct supervision of a doctor. For more information, see the package leaflet or contact your doctor or pharmacist.

How does Lonquex work?

The active substance in Lonquex, lipegfilgrastim, is similar to granulocyte colony stimulating factor (G–CSF), a naturally occurring protein in the body that stimulates the production of white blood cells including neutrophils in the bone marrow. Lipegfilgrastim acts in the same way as G–CSF, increasing the production of neutrophils and thereby helping to reduce the duration of neutropenia and the occurrence of febrile neutropenia in patients receiving chemotherapy.

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Lipegfilgrastim is a form of filgrastim, which has been available in the EU for a number of years. In Lonquex, filgrastim has been 'pegylated' (attached to a chemical called polyethylene glycol). This slows down the medicine's removal from the body and allows the medicine to be given less often.

What benefits of Lonquex have been shown in studies?

Lonquex was effective in reducing the duration of neutropenia and the number of febrile neutropenia cases among patients undergoing chemotherapy. In a main study involving 202 women with breast cancer, Lonquex compared well with another pegylated filgrastim: the average duration of severe neutropenia during chemotherapy was around 17 hours with Lonquex compared with around 19 hours with the other medicine. Lonquex also compared well with the other medicine in the number of febrile neutropenia cases: 1 in the Lonquex-treated group versus 3 in the comparator group.

Another main study in 376 adult patients compared Lonquex with placebo (a dummy treatment). Patients receiving Lonquex recovered from neutropenia more quickly and fewer patients suffered severe neutropenia.

Data on the way Lonquex works in the body showed that when given at the recommended dose to children aged 2 to 17 years who are receiving chemotherapy, the medicine is expected to lead to similar responses to those seen in adults.

In addition, the effect of Lonquex on febrile neutropenia was investigated in two studies involving a total of 63 children between 2 and 17 years old with Ewing sarcoma (a cancer of the bone or nearby soft tissue) or rhabdomyosarcoma (a type of soft tissue cancer) who were undergoing chemotherapy. In the first study, febrile neutropenia occurred in 20% (4 out of 20) of the patients after one dose of Lonquex, which is comparable to the frequency seen with approved filgrastim treatments in children.

In the second study, febrile neutropenia occurred in 35% (7 out of 20) of patients who received Lonquex compared with 42% (8 out of 19) of those given filgrastim. In addition, the average duration of febrile neutropenia seen with Lonquex was comparable to that seen with filgrastim (2.7 and 2.5 days, respectively).

What are the risks associated with Lonquex?

The most common side effects with Lonquex (which may affect more than 1 in 10 patients) are nausea as well as bone and muscle pain. For the full list of side effects of Lonquex, see the package leaflet.

Why is Lonquex authorised in the EU?

Lonquex has been shown to be effective in reducing the duration of severe neutropenia and the number of febrile neutropenia cases in adults. Lonquex has also been shown to behave in the same way in children aged 2 to 17 years as in adults and to show similar effects to a filgrastim treatment already approved in children. In addition, the less frequent dosing with Lonquex compared with that of filgrastim treatments for children is considered an advantage due to a lower treatment burden. The side effects of the medicine were typical for this class of medicines and are considered manageable. The Agency therefore decided that Lonquex'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 Lonquex?

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

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

Other information about Lonquex

Lonquex received a marketing authorisation valid throughout the EU on 25 July 2013.

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

This overview was last updated in 07-2022