European Medicines Agency

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EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

NEUPOPEG

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.
If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Neupopeg?

Neupopeg is a solution for injection that contains the active ingredient pegfilgrastim. It is available in a pre-filled syringe and a pre-filled pen (SureClick), each containing 6 mg pegfilgrastim.

What is Neupopeg used for?

Neupopeg is used in cancer patients to help with some of the side effects of their treatment. Chemotherapy (cancer treatment) that is cytotoxic (cell-killing) also kills white blood cells, which can lead to neutropenia (low white blood cell counts) and the development of infections. Neupopeg is used to reduce the duration of neutropenia and the occurrence of febrile neutropenia (neutropenia with fever).
Neupopeg can be used for many types of cancer, except for chronic myeloid leukaemia (a cancer of the white blood cells). It also cannot be used in patients with myelodysplastic syndromes, a disease in which too many white blood cells are produced, and which can develop into leukaemia.
The medicine can only be obtained with a prescription.

How is Neupopeg used?

Neupopeg treatment should be initiated and supervised by a doctor who has experience in the treatment of cancer or blood disorders. Neupopeg is given as a single 6 mg injection under the skin around 24 hours after the end of each cycle of chemotherapy. Patients can inject themselves if they have been trained appropriately. Neupopeg is not recommended for use in children, due to a lack of information on its safety and effectiveness in this group.

How does Neupopeg work?

The active substance in Neupopeg, pegfilgrastim, is an immunostimulant that belongs to the group 'colony stimulating factors'. It consists of filgrastim, a copy of a human protein called granulocyte colony stimulating factor (G-CSF), which has been 'pegylated' (coated with a chemical called polyethylene glycol). Filgrastim works by encouraging the bone marrow to produce more white blood cells, increasing white blood cell counts and treating neutropenia. Filgrastim has been available in other medicines in the European Union (EU) for a number of years. Because it is pegylated in pegfilgrastim, the rate at which the medicine is removed from the body is decreased, allowing the medicine to be given less often.

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The filgrastim in Neupopeg is produced by a method known as 'recombinant DNA technology': it is made by a bacterium that has received a gene (DNA), which makes it able to produce filgrastim. The replacement acts in same way as naturally produced G-CSF.

How has Neupopeg been studied?
Neupopeg has been studied in two main studies involving 467 patients with breast cancer who were being treated with cytotoxic chemotherapy. In both studies, the effectiveness of a single injection of Neupopeg 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.

What benefit has Neupopeg shown during the studies?
Neupopeg 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.

What is the risk associated with Neupopeg?
Most of the side effects seen in patients taking Neupopeg in studies are due to their underlying disease or chemotherapy. The most common side effects with Neupopeg (seen in more than 1 in 10 patients) are bone pain and raised levels of lactate dehydrogenase (a marker of red blood cell breakdown). For the full list of all side effects reported with Neupopeg, see the Package Leaflet.
Neupopeg should not be used in people who may be hypersensitive (allergic) to pegfilgrastim or any of the other ingredients.

Why has Neupopeg been approved?
The Committee for Medicinal Products for Human Use (CHMP) decided that Neupopeg's benefits are greater than its risks for the reduction of the duration of neutropenia and the incidence of febrile neutropenia in patients treated with cytotoxic chemotherapy for malignancy. The Committee recommended that Neupopeg be given marketing authorisation.

Other information about Neupopeg:
The European Commission granted a marketing authorisation valid throughout the EU for Neupopeg to Dompé Biotec S.p.A. on 22 August 2002. The marketing authorisation was renewed on 22 August 2007.

The full EPAR for Neupopeg can be found here.

This summary was last updated in 02-2008.