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EPAR summary for the public

Ristempa

pegfilgrastim

This is a summary of the European public assessment report (EPAR) for Ristempa. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Ristempa.

For practical information about using Ristempa, patients should read the package leaflet or contact their doctor or pharmacist.

What is Ristempa and what is it used for?

Ristempa is a medicine used in cancer patients to help with some of the side effects of their treatment. Chemotherapy (medicines to treat cancer) that is cytotoxic (cell-killing) also kills white blood cells, which can lead to neutropenia (low levels of neutrophils, a type of white blood cell that fights infections) and the development of infections. Ristempa is used to reduce the duration of neutropenia and the occurrence of febrile neutropenia (neutropenia with fever).

Ristempa cannot be used in patients with 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, which can develop into leukaemia).

Ristempa contains the active substance pegfilgrastim. This medicine is the same as Neulasta, which is already authorised in the European Union (EU). The company that makes Neulasta has agreed that its scientific data can be used for Ristempa ('informed consent').

How is Ristempa used?

Ristempa 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.

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Ristempa is available as a solution for injection in pre-filled syringes containing 6 mg pegfilgrastim. It 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.

How does Ristempa work?

The active substance in Ristempa, pegfilgrastim, consists of filgrastim, which is very similar to a human protein called granulocyte colony stimulating factor (G-CSF), that has been 'pegylated' (attached to a chemical called polyethylene glycol). Filgrastim works by stimulating 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.

What benefits of Ristempa have been shown in studies?

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

Ristempa 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, compared with around five to seven days when neither medicine is used.

What are the risks associated with Ristempa?

The most common side effects with Ristempa (seen in more than 1 in 10 patients) are bone and muscle pain, headache and nausea (feeling sick). For the full list of all side effects and restrictions, see the package leaflet.

Why is Ristempa approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Ristempa's benefits are greater than its risks and recommended that it be approved for use in the EU.

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

A risk management plan has been developed to ensure that Ristempa is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Ristempa, including the appropriate precautions to be followed by healthcare professionals and patients.

Further information can be found in the summary of the risk management plan.

Other information about Ristempa

The European Commission granted a marketing authorisation valid throughout the European Union for Ristempa on 13 April 2015.

The full EPAR and risk management plan summary for Ristempa can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Ristempa, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 04-2015.