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Ryzneuta (*efbemalenograstim alfa*)

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

What is Ryzneuta and what is it used for?

Ryzneuta is a medicine that stimulates the production of white blood cells. 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 receiving cytotoxic chemotherapy (medicines to treat cancer by killing cells).

Ryzneuta is not intended for use in patients with chronic myeloid leukaemia or myelodysplastic syndromes (conditions in which large numbers of abnormal blood cells are produced).

Ryzneuta contains the active substance efbemalenograstim alfa.

How is Ryzneuta used?

Ryzneuta 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 given as an injection under the skin at least 24 hours after the end of each cycle of chemotherapy.

For more information about using Ryzneuta, see the package leaflet or contact your doctor or pharmacist.

How does Ryzneuta work?

Chemotherapy can cause neutropenia, which may increase the risk of infections. The active substance in Ryzneuta, efbemalenograstim alfa, is very similar to a protein called granulocyte colony-stimulating factor (G-CSF), which is involved in the production of white blood cells in the bone marrow. Ryzneuta works like G-CSF and helps the bone marrow make more white blood cells, thereby treating neutropenia.

What benefits of Ryzneuta have been shown in studies?

The benefits of Ryzneuta were investigated in three main studies involving patients receiving myelotoxic chemotherapy (medicines to treat cancer that kill blood cells) to treat breast cancer. The studies measured the number of days in which patients had severe neutropenia after starting chemotherapy.

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In a study involving 122 patients, those given Ryzneuta experienced an average of 2.9 fewer days of severe neutropenia compared with patients given placebo (a dummy treatment): 1.3 days and 3.9 days, respectively.

In a second study involving 393 patients, patients given Ryzneuta were compared with patients given pegfilgrastim (another medicine to treat neutropenia which, like Ryzneuta, is also given once per chemotherapy cycle): both groups experienced 0.2 days with severe neutropenia on average.

A third study was carried out in 242 women who needed chemotherapy after surgery for breast cancer. In this study, patients given Ryzneuta and patients given filgrastim (another medicine to treat neutropenia, which is given once a day) experienced 0.7 days of severe neutropenia on average.

What are the risks associated with Ryzneuta?

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

Side effects with Ryzneuta mostly concern pain in bone and muscles. The most common side effect (which may affect more than 1 in 10 people) is bone pain. Other side effects (which may affect up to 1 in 10 people) include pain in the back, joints and extremities (arms, hands, legs and feet).

Why is Ryzneuta authorised in the EU?

In patients given chemotherapy to treat their cancer, Ryzneuta reduced the duration of severe neutropenia as much as pegfilgrastim and filgrastim (other available treatments) and no new safety concerns were identified compared to what is known of other G-CSF medicines used in clinical practice. The European Medicines Agency decided that Ryzneuta'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 Ryzneuta?

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

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

Other information about Ryzneuta

Ryzneuta received a marketing authorisation valid throughout the EU on 21 March 2024.

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

This overview was last updated in 03-2024.