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Minjuvi (*tafasitamab)*

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

What is Minjuvi and what is it used for?

Minjuvi is a cancer medicine used first in combination with another medicine called lenalidomide, and then on its own, to treat adults with diffuse large B-cell lymphoma (DLBCL) whose cancer has returned or has stopped responding to other treatments and who cannot have an autologous stem cell transplantation (a transplant where the stem cells are collected from the patients themselves).

DLBCL is rare, and Minjuvi was designated an 'orphan medicine' (a medicine used in rare diseases) on 15 January 2015. Further information on the orphan designation can be found here: https://www.ema.europa.eu/en/medicines/human/orphan-designations/eu3141424.

Minjuvi contains the active substance tafasitamab.

How is Minjuvi used?

Minjuvi can only be obtained with a prescription and must be given by a healthcare professional experienced in cancer treatment. The medicine is available as a powder to be made into a solution for infusion (drip) into a vein.

Minjuvi treatment is given over cycles of 28 days, with the infusion given on certain days of each cycle. The dose is based on body weight. The doctor may adjust or stop treatment based on the patient's reaction to the infusion. Minjuvi is given with lenalidomide for up to 12 cycles, after which Minjuvi can be given alone. Treatment continues until the disease progresses or side effects become unacceptable.

Patients are also given medicines to reduce the risk of reactions to the infusion before each dose of Minjuvi, for at least the first 3 infusions.

Any infection should be treated before starting treatment with Minjuvi.

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

How does Minjuvi work?

The active substance in Minjuvi, tafasitamab, is a monoclonal antibody, a type of protein that is designed to recognise and attach to a specific structure on certain cells in the body. Tafasitamab in

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particular, was designed to attach to CD19, a protein that is present on the surface of the cancer cells. When attached to CD19, the medicine is expected to stimulate the immune system (the body's natural defences) to attack and kill the cancer cells and thereby slow down the progression of the disease.

What benefits of Minjuvi have been shown in studies?

Minjuvi used in combination with lenalidomide was investigated in a study involving 81 adult patients with DLBCL that did not respond to other treatments and who could not have an autologous stem cell transplantation. In this study, patients were treated with Minjuvi and lenalidomide for up to 12 cycles followed by Minjuvi on its own until the disease progressed or side effects became unmanageable. Of the patients involved in the study, 46 (57%) had either a complete response (no sign of cancer) or a partial response.

What are the risks associated with Minjuvi?

The most common side effects with Minjuvi (which may affect more than 1 in 10 people) are infections, neutropenia (low white blood cell count), anaemia (low red blood cell count), thrombocytopaenia (low blood platelet count), diarrhoea, weakness, cough, peripheral oedema (swelling especially of the ankles and feet), fever and decreased appetite.

The most common serious side effects (which may affect more than 1 in 100 people) are infection, including pneumonia (infection of the lungs), and neutropenia with fever.

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

Why is Minjuvi authorised in the EU?

Patients with DLBCL whose cancer has returned or does not respond to treatment and who cannot have an autologous stem cell transplantation have limited treatment options. Minjuvi together with lenalidomide was shown to provide a clinically meaningful response and the side effects were manageable. The European Medicines Agency therefore decided that Minjuvi's benefits are greater than its risks and it can be authorised for use in the EU.

Minjuvi has been given 'conditional authorisation'. This means that there is more evidence to come about the medicine, which the company is required to provide. Every year, the European Medicines Agency will review any new information that becomes available and this overview will be updated as necessary.

What information is still awaited for Minjuvi?

Since Minjuvi has been given conditional authorisation, the company that markets Minjuvi will provide evidence from three additional studies on the safety and efficacy of the medicine in combination with lenalidomide or bendamustine (another cancer medicine) in patients with DLBCL.

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

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

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

Other information about Minjuvi

Minjuvi received a conditional marketing authorisation valid throughout the EU on 26 August 2021

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

This overview was last updated in 08-2021.