EMADOC-1829012207-35933
EMEA/H/C/005436

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 medicine used to treat adults with:

- diffuse large B-cell lymphoma, an aggressive cancer of B cells (a type of white blood cells), in patients whose cancer has returned or has stopped responding to other treatments, and who cannot have an autologous stem cell transplantation (a transplant of blood-forming cells using the patient's own cells). For diffuse large B-cell lymphoma, Minjuvi is first given together with lenalidomide (another cancer medicine) and then on its own.
- follicular lymphoma, a cancer of B cells, in patients with grade 1 to 3a disease whose cancer has returned or stopped responding after at least one previous treatment. For follicular lymphoma, Minjuvi is given together with the cancer medicines lenalidomide and rituximab.

Diffuse large B cell lymphoma and follicular lymphoma are rare, and Minjuvi was designated an 'orphan medicine' (a medicine used in rare diseases). Further information on the orphan designations can be found on the EMA website (diffuse large B cell lymphoma: 15 January 2015; follicular lymphoma: 26 February 2025).

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 the treatment of cancer.

Minjuvi is given by infusion (drip) into a vein in cycles of 28 days, with the infusion given on specific days of each cycle. For the treatment of diffuse large-B cell lymphoma, Minjuvi is given with lenalidomide for up to 12 cycles, after which Minjuvi is continued for as long as the patient benefits from treatment or until the side effects become too severe. For the treatment of follicular lymphoma, Minjuvi is given with lenalidomide for up to 12 cycles, and patients also receive rituximab for the first 5 cycles.

To reduce the risk of infusion-related reactions, patients should be given other medicines before treatment with Minjuvi. For patients who do not have a reaction to the first three infusions, the doctor

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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may decide that these medicines are not needed for subsequent infusions. If the patient has side effects during an infusion, the infusion should be temporarily stopped.

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 made to attach to a target in the body. Tafasitamab targets and attaches to CD19, a protein found on B cells, including cancerous B cells. When tafasitamab attaches to CD19, the medicine stimulates the immune system (the body's natural defences) to attack and kill the cancer cells, thereby slowing down the progression of the cancer.

What benefits of Minjuvi have been shown in studies?

Diffuse large B-cell lymphoma

Minjuvi was investigated in a main study involving 81 adults with diffuse large B-cell lymphoma who had not responded or stopped responding to treatment, and who could not have an autologous stem cell transplantation. In this study, Minjuvi was not compared with another treatment or with placebo (a dummy treatment). Participants received Minjuvi and lenalidomide for up to 12 cycles, followed by Minjuvi on its own until the disease got worse or side effects became unmanageable. Overall, 57% (46 out of 81) of participants had either a complete response (no detectable sign of cancer) or a partial response (the cancer became smaller). The study was not designed to reliably evaluate how long patients lived.

The results from this main study were compared with results from other studies which evaluated Minjuvi or lenalidomide alone.

Follicular lymphoma

Minjuvi was investigated in a main study involving 548 adults with Grade 1 to 3a follicular lymphoma who had not responded or stopped responding to at least one previous treatment. Participants received Minjuvi or placebo together with lenalidomide for 12 cycles and rituximab for 5 cycles. On average, participants given Minjuvi lived for around 22 months without their disease getting worse, compared with around 14 months for those given placebo. Information on how long patients lived overall was not yet available.

What are the risks associated with Minjuvi?

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

For the treatment of diffuse large B-cell lymphoma, the most common side effects with Minjuvi (which may affect more than 1 in 10 people) include infections, neutropenia (low levels of neutrophils, a type of white blood cell), anaemia (low levels of red blood cells), thrombocytopenia (low levels of platelets in the blood), diarrhoea, weakness, cough, peripheral oedema (swelling especially of the ankles and feet), fever and decreased appetite. Some side effects can be serious. The most frequent serious side effects with Minjuvi (which may affect more than 1 in 100 people) include infections (including pneumonia, an infection of the lungs) and neutropenia with fever.

For the treatment of follicular lymphoma, the most common side effects with Minjuvi (which may affect more than 1 in 10 people) include infection, including viral and bacterial infections, neutropenia, rash, weakness, fever, thrombocytopenia, anaemia, infusion-related reactions, itching and headache. The most frequent serious side effects (which may affect more than 1 in 100 people) include infections, including viral and bacterial infections, neutropenia with fever, sudden kidney damage and fever.

Why is Minjuvi authorised in the EU?

At the time of authorisation, people with diffuse large B-cell lymphoma whose cancer had returned or stopped responding to treatment and who cannot have an autologous stem cell transplantation had limited treatment options. In the main study, Minjuvi given with lenalidomide led to benefits in more than half of participants. Because the treatment was not directly compared with another medicine or placebo, there is some uncertainty about how large the benefit is. Side effects with Minjuvi, such as infections and low levels of white blood cells, are commonly seen with treatments for cancers of B cells and were considered manageable.

In people with follicular lymphoma whose cancer has come back or stopped responding to at least one previous medicine, Minjuvi given with lenalidomide and rituximab helped them live longer without their disease getting worse. Adding Minjuvi to lenalidomide and rituximab led to a higher risk of severe neutropenia and severe infections. However, because the treatment offers benefits for patients, these risks were considered acceptable.

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 it has been authorised on the basis of less comprehensive data than are normally required because it fulfils an unmet medical need. The agency considers that the benefit of having it available earlier outweighs any risks associated with using it while awaiting further evidence.

The company must provide further data on Minjuvi. It must submit the results from two studies in patients with diffuse large B-cell lymphoma to confirm the medicine's effectiveness and safety. Every year, the Agency will review any new information that becomes available.

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. Suspected side effects reported with Minjuvi 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 12-2025.