swissmedic

Summary report on authorisation dated 10 April 2026

Minjuvi® (active substance: tafasitamab)

Indication extension in Switzerland: 19 December 2025

Powder for solution for infusion in combination with lenalidomide and rituximab for the treatment of adults with relapsed or refractory follicular lymphoma (FL) after at least one prior line of systemic therapy.

About the medicinal product

Minjuvi is a cancer medicine containing the active substance tafasitamab.

Minjuvi was first authorised by Swissmedic on 22 March 2022 as combination therapy with lenalidomide for the treatment of adults with recurrent or refractory diffuse large B-cell lymphoma who are not eligible for a stem cell transplant.

The current indication extension means that Minjuvi can now also be used in combination with lenalidomide and rituximab for the treatment of adult patients with follicular lymphoma (FL), whose disease has recurred after at least one prior line of systemic therapy or has not responded to treatment. Lenalidomide (an immunomodulating agent) and rituximab (a monoclonal antibody against the CD20 antigen) are also both cancer medicines.

Follicular lymphoma is a slow-growing form of non-Hodgkin lymphoma that accounts for around 10–20 % of all non-Hodgkin lymphomas. Although the disease often responds well to initial treatment, it is currently considered to be incurable. Since many sufferers experience relapses (recurrences) over time, multiple lines of treatment are often needed.

The available treatment options are limited for patients whose disease recurs following treatment or who fail to respond adequately to first-line treatment.

Since follicular lymphoma is a rare and life-threatening disease, the medicine has been authorised as an orphan drug. The term "orphan drug" is used to refer to important medicines for rare diseases.

Mode of action

Tafasitamab, the active substance in Minjuvi, is a modified monoclonal antibody (immunologically active protein).

The monoclonal antibody binds to a specific receptor (target site), the CD19 antigen on the surface of the precursor cells of B cells and the B cells themselves. After binding to CD19, tafasitamab causes the B cells to be destroyed by the body's own immune system, thereby inhibiting the growth of the cancer.

Administration

Minjuvi is a prescription-only medicine and is authorised as a vial containing 200 mg of tafasitamab powder.

The recommended dose is 12 mg per kg body weight administered as an intravenous infusion.

For the treatment of follicular lymphoma, Minjuvi is used in combination with two other medicinal products:

- lenalidomide, taken in capsule form
- rituximab, which is also administered as an infusion

The treatment with Minjuvi is administered in 28-day cycles, with up to twelve cycles with lenalidomide and five cycles with rituximab.

Before the initial infusions, patients usually receive premedication (e.g. antipyretics, antihistamines or corticosteroids) to prevent infusion-related reactions.

Efficacy

The efficacy of Minjuvi in the treatment of follicular lymphoma was investigated in the clinical trial INCMOR 0208-301 (inMIND).

548 adult patients with relapsed or refractory follicular lymphoma took part in this trial. In all participants, the disease had recurred after at least one prior treatment or had not responded adequately to the treatment. Additionally, all patients had previously received anti-CD20 therapy.

The participants were randomly assigned to one of two groups. One group received Minjuvi in combination with lenalidomide and rituximab, while the control group received a placebo (dummy drug) instead of Minjuvi, but was likewise given lenalidomide and rituximab. The treatment was administered for up to twelve cycles of 28 days each.

The primary endpoint for assessing efficacy was progression-free survival (PFS)[1]. The study showed that the combination with Minjuvi significantly delayed disease progression:

Patients in the Minjuvi group lived for a median of around 22 months without further progression of the disease, compared to around 14 months for those in the control group.

Also determined was the PET-CR rate, which describes the proportion of patients whose PET scan no longer showed any detectable active cancer. In the study, some 49 % of the patients achieved this complete remission with Minjuvi, compared to around 40 % without Minjuvi, which represents a statistically significant advantage.

[1] PFS: progression-free survival. period between the start of a treatment or a clinical trial and the onset of disease progression or the death of the patient.

While conclusive data on overall survival[2] were not available at the time of the assessment, the data available to date do not show any disadvantage of the treatment with Minjuvi compared to the control group. Such data will continue to be collected and assessed.

Precautions, undesirable effects, & risks

Minjuvi must not be used in those who are hypersensitive to the active substance or any of the excipients.

The most common undesirable effects (affecting more than 1 in 10 users) include infections, neutropenia (greatly reduced count of certain white blood cells), diarrhoea, rash, feeling of weakness, constipation, fever, thrombocytopenia (reduced platelet count), anaemia, cough and headache.

Since infections, infusion-related reactions (e. g. chills or breathing problems) and changes in blood test results can occur during treatment, regular checks and close medical monitoring are required.

Serious complications can occur in rare cases, including progressive multifocal leukoencephalopathy (PML), a rare viral infection of the brain, or secondary cancers. Therefore, doctors should look out for corresponding warning signs.

All precautions, risks, and other possible undesirable effects are listed in the Information for healthcare professionals.

Why the medicinal product has been authorised

Follicular lymphoma is a slow-growing, but currently incurable, form of lymph node cancer. Many patients experience multiple relapses as the disease progresses. There is a great medical need for effective treatment options particularly for sufferers whose disease recurs after prior treatments or fails to respond adequately to the treatment.

The pivotal study demonstrated the ability of the combination of Minjuvi, lenalidomide and rituximab to slow the progression of the disease to a clinically significant extent and lead to a reduction of disease symptoms more frequently than treatment without Minjuvi.

While definitive results on overall survival were not available at the time of the assessment, the data available to date do not show any disadvantage compared to the control treatment and suggested a possible positive effect. Further data will continue to be collected and assessed.

The known risks of the treatment, including infections, changes in blood test results or infusion-related reactions, are considered to be manageable with corresponding medical monitoring and appropriate precautions.

Taking all the risks and precautions into account, and based on the available data, the benefits of Minjuvi outweigh the risks. Swissmedic has therefore authorised the medicinal product Minjuvi, containing the active substance tafasitamab, in combination with lenalidomide and rituximab for the treatment, in Switzerland, of patients with relapsed or refractory follicular lymphoma.

[2] Overall survival (OS): overall survival refers to the period between the start of treatment and the death of the patient.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Minjuvi®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.

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