MINJUVI®
tafasitamab

Information for patients

MINJUVI® is used in combination with lenalidomide followed by MINJUVI® monotherapy for the treatment of adult patients with relapsed or refractory **diffuse large B-cell lymphoma** (DLBCL) after at least one prior line of systemic therapy, including an anti-CD20 antibody, who are not eligible for autologous stem cell transplant (ASCT).

Only to be handed out by the treating physician for patients who have already been prescribed tafasitamab.

Incyte

Contents

Dear Patient,

Your doctor has prescribed tafasitamab (MINJUVI®) for you.
MINJUVI® is the trade name for a medicine containing the active substance tafasitamab. In order to make this booklet easier for you to read, we will only be using the active substance name tafasitamab in the following pages. The content of this booklet is intended to provide you with information to accompany your treatment.

This booklet cannot and should not replace a personal conversation with your doctor, and you should also read the package insert. Please take the time to read this booklet and the package insert. While reading, please make a note of any questions you may have, and please discuss these during your next visit to your doctor.

What is diffuse large B-cell lymphoma (DLBCL)?

Lymphomas are diseases that can develop from lymphatic organs, such as the lymph nodes and spleen, or from lymphatic cells (T-cells and B-cells).

Diffuse large B-cell lymphoma is an aggressive form of blood cancer that affects mature B-cells (B-lymphocytes). These are a type of white blood cell normally responsible for specific defense against pathogens of disease. In their healthy state, B-cells recognize pathogens such as viruses and bacteria and produce antibodies against them. In this way, they make it possible to fight off these pathogens.

In diffuse large B-cell lymphoma, some of these B-cells have pathological changes and develop into tumor cells. They change their shape and also increase in number in an uncontrollable manner, for example in the lymph nodes or the spleen. This can also lead to enlargement of the lymph nodes or the spleen.

If the disease spreads to the bone marrow, this can also disrupt the normal production of blood cells. This can become apparent in the following ways:

- Drop in the number of red blood cells, which can lead to symptoms such as tiredness and fatigue.
- Reduced number of blood platelets, which can result in an increased tendency to bleed.
- The function of white blood cells may be impaired, and this may be associated with an increased susceptibility for infection.

What is tafasitamab?

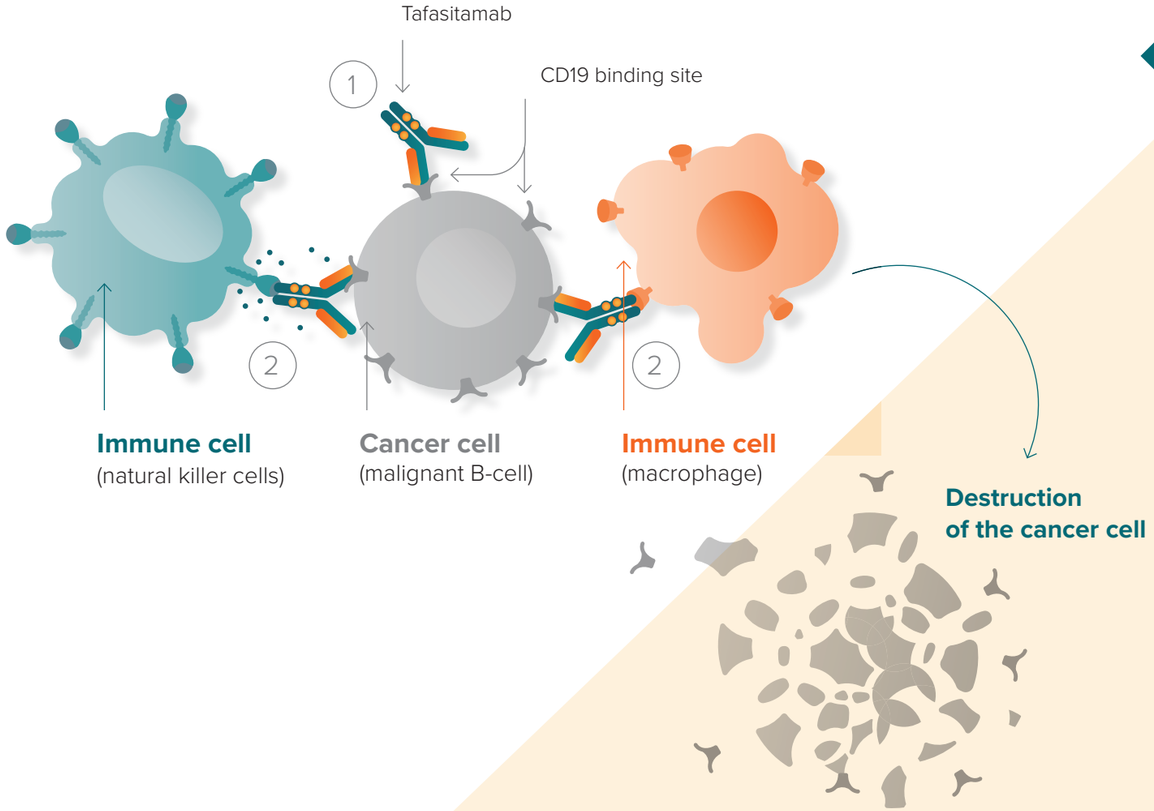
Tafasitamab belongs to the drug class of antibodies.
Antibodies are a special type of protein that can act in a targeted manner against certain structures on the surface of tumor cells.

In this case, the antibody tafasitamab targets a surface structure known as “CD19” that can be found on B-cells.

1. Tafasitamab recognizes and binds to the CD19 structure on the surface of normal and diseased B-cells (tumor cells).

2. By doing this, tafasitamab marks the tumor cells for the immune system, which can then identify and remove them.

In the treatment of diffuse large B-cell lymphoma, antibodies are normally used in combination with other medicines. Tafasitamab is used in combination with the medicine lenalidomide.

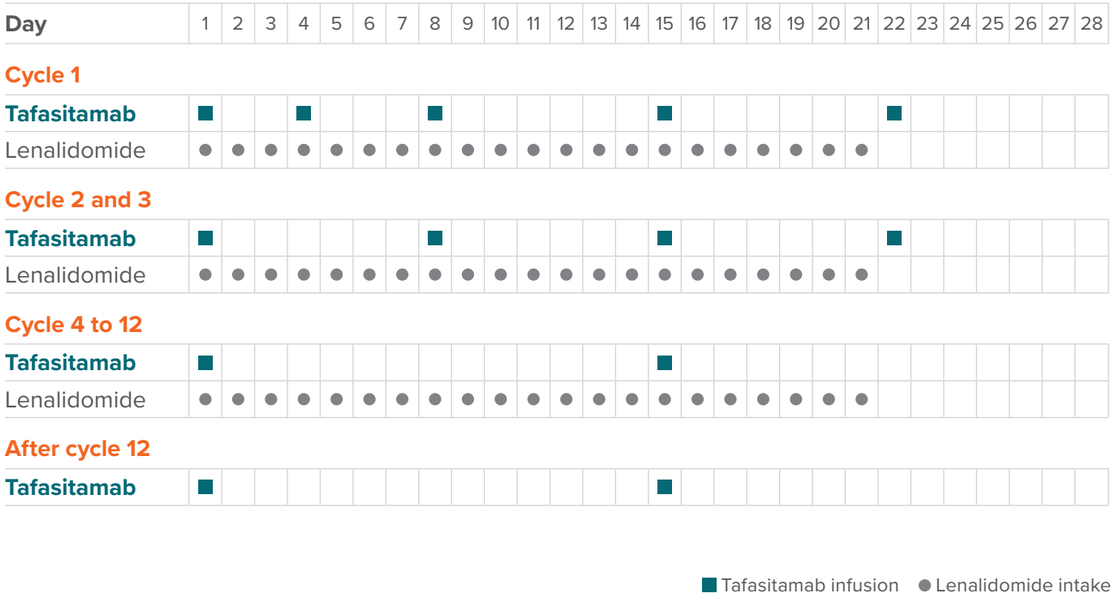


How are tafasitamab and lenalidomide used?

Tafasitamab is used for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma who are not eligible for stem cell transplant.

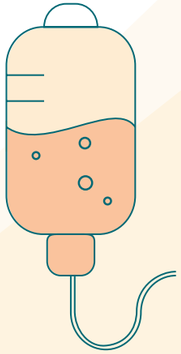
In the first phase of treatment, tafasitamab is used in combination with lenalidomide. Lenalidomide is also a cancer drug, and it supports the action of the antibody tafasitamab.

The table opposite shows the planned treatment regimen for your treatment with tafasitamab in combination with lenalidomide. One treatment cycle lasts 4 weeks (28 days).



Treatment cycle 1 up to max. treatment cycle 12: In the first phase of treatment, tafasitamab is administered together with lenalidomide. The squares in the table show the days on which the infusion of tafasitamab is given, and the dots show the days on which lenalidomide is taken.

After the 12th cycle of treatment: Tafasitamab is now continued alone, i.e., as monotherapy. The squares in the table show the days on which the infusion of tafasitamab is given.



Tafasitamab: Infusion

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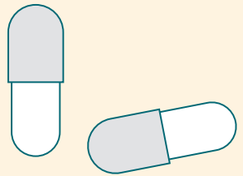


Lenalidomide: Capsules

In what form are the medicines administered?

Tafasitamab is given as an infusion. You will be given this in your doctor's clinic. Your first infusion will normally last about 2.5 hours, and the subsequent infusions will last between about 1.5 and 2 hours. When you come to your infusion appointments, wear some comfortable clothes and perhaps bring something for you to do, for example read a book. You will be accompanied by a healthcare professional at all times during and after the infusion. This person will also be available to answer your questions at any time.

Infusion-related reactions: Infusion-related reactions may occur during the treatment with tafasitamab. These are most likely to occur during the first infusion. Therefore, you may be given medicines to reduce the risk of these infusion-related reactions (pre-medication) between 30 minutes and 2 hours prior to the tafasitamab infusion. This pre-medication is recommended at the first three infusions and is optional after this.

Lenalidomide is given orally in the form of capsules. You should take the capsules whole, together with a glass of water, and with or without a meal. Please make sure that you take the lenalidomide at approximately the same time of day on the scheduled days of treatment.

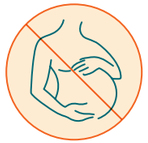
What do I need to pay attention to as part of the treatment?

You should discuss the following points with your doctor before the start of treatment:

Using tafasitamab together with other medicines:

Tell your doctor if you are currently using, have recently used or intend to use any other medicines to treat another illness. This also includes, for example, prescription-free medicines, such as herbal or homeopathic medicines, and also dietary supplements.

The use of live vaccines is not recommended during treatment with tafasitamab.



Pregnancy and breast-feeding:

- It is recommended that women of child-bearing age **use a reliable birth control method** during treatment with tafasitamab and for at least 3 months after the end of treatment.
- Tafasitamab must not be used during pregnancy or by women of child-bearing age who are not using birth control. **Pregnancy must be ruled out before treatment.** Tell your doctor straight away if you become pregnant or suspect you may be pregnant during treatment with tafasitamab.
- You must **not breast-feed** during treatment with tafasitamab and **for up to at least 3 months after the last dose.** It is not known whether tafasitamab is excreted in mother‘s milk.
- Tafasitamab is given together with lenalidomide for up to 12 cycles. **Lenalidomide can harm the unborn child and must not be used during pregnancy or in women of child-bearing age,** unless all of the conditions of the Lenalidomide Pregnancy Prevention Program are met. Your doctor will give you further information and recommendations.

Please ask your doctor to explain the possible side effects associated with lenalidomide.

What side effects may occur?

Like all medicines, this medicine can cause side effects, although not everybody gets them.

This booklet does not mention all of the possible side effects.
Please also read the instructions for use (package insert) and talk to your treating physician to get a more detailed picture of the possible side effects.

Be vigilant for signs or symptoms of infection. These may be new symptoms, or a change in your current symptoms.

They may require urgent medical treatment. If you experience the following serious side effects, **inform your doctor or a healthcare professional immediately.**

Serious infections, such as a lung infection (pneumonia) or an infection of the bloodstream (sepsis).

These may manifest with the following symptoms:

Fever,
chills

Nausea, vomiting,
diarrhea

Sore throat,
cough, shortness of breath

These symptoms may be particularly severe if you have been told that you have a low number of white blood cells (in particular the sub-group of white blood cells known as neutrophils).

Other side effects that have occurred in more than 1 in 10 patients are:

Fever of 38°C or higher, or symptoms of an infection:
This can be a sign of a reduced number of white blood cells.

Unusual bruising or bleeding, including after minor injury:
This can be a sign of a reduced number of
blood platelets (thrombocytes).

Pale skin or lips, tiredness, shortness of breath:
This can be a sign of a reduced number of red blood cells.

Bacterial, viral or fungal infections, such as infections of the respiratory tract, bronchitis, pneumonia, urinary tract infections, rash, low potassium levels in blood tests, muscle cramps, back pain, swelling of the arms and/or legs due to fluid collection, weakness, tiredness, general malaise, fever, diarrhea, constipation, stomach pain, nausea, vomiting, cough, shortness of breath, reduced appetite.

Contact your doctor or a healthcare professional if you notice one of the side effects described above.

Reporting of side effects

If you get any side effects, talk to your doctor.

This includes any possible side effects not listed in the instructions for use (package insert). Side effects can be reported directly via Swissmedic using an online form available at www.swissmedic.ch / Contact / General questions.
This contact form does not replace the need to talk to your doctor.

By reporting side effects you can help provide more information on the safety of this medicine.

Glossary

Antibodies:
Antibodies are a special type of protein that can act in a targeted manner against certain structures on the surface of tumor cells.

B-cells or B-lymphocytes:
Lymphocytes are a sub-group of leukocytes (white blood cells). Their main task in the human body is to fight pathogens of disease. However, their activity is also targeted against abnormal body cells, e.g., tumor cells.

B-cell lymphoma:
This is a cancer affecting B-lymphocytes, a sub-group of white blood cell.

DLBCL:
Diffuse Large B-Cell Lymphoma.

CD19:
CD19 is a surface structure on B-cells. In your treatment, tafasitamab recognizes and binds to the CD19 structure on the surface of diseased B-cells (tumor cells).

Glossary

Infusion:
Administration of a medicine in liquid form into a vein in your body.

Lenalidomide:
Lenalidomide is also a cancer drug, and as part of your therapy it is used to support the action of the antibody tafasitamab.

Monotherapy:
Treatment of a disease using one medicine alone, in contrast to combination therapy with, for example, two medicines.

Neutrophils:
Neutrophils, also known as neutrophilic granulocytes, are the largest sub-group of leukocytes (white blood cells). They can be measured using a blood count test. Their main task in the human body is to fight pathogens of disease.

Tafasitamab:
Active substance in the medicine MINJUVI®.

Thrombocytes:
Thrombocytes (also known as blood platelets) are the smallest cells in the blood and play an important role in blood clotting.

Notes

Notes

CH/MJVI/NP/24/0003
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