MINJUVI®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details.

1. Why am I using MINJUVI?

MINJUVI contains the active ingredient tafasitamab. MINJUVI is used to treat adults with a cancer of B cells called diffuse large B-cell lymphoma.

For more information, see Section 1. Why am I using MINJUVI? in the full CMI.

2. What should I know before I use MINJUVI?

Do not use if you have ever had an allergic reaction to tafasitamab or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use MINJUVI? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with MINJUVI and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How is MINJUVI given?

- The recommended dose is 12 mg tafasitamab per kilogram body weight during specified cycles.
- MINJUVI will be given to you as an infusion (a drip) into a vein (intravenously) over a period of 150 minutes for the first infusion, and between 90 and 120 minutes for all subsequent infusions.
- In addition, your doctor will prescribe lenalidomide capsules (starting dose of lenalidomide is 25 mg daily) for up to twelve cycles.

More instructions can be found in Section 4. How do I use MINJUVI? in the full CMI.

5. What should I know while using MINJUVI?

Things you must do	• If you are about to be started on any new medicine, remind your doctor that you are being given MINJUVI • Remind any doctor, dentist or pharmacist you visit that you are using MINJUVI • If you become pregnant while being given this medicine, tell your doctor immediately
Things you must not do	• During your treatment with MINJUVI you may feel tired and experience loss of strength. Do not drive or use any tools or machines if you are experiencing any of these side effects

For more information, see Section 5. What should I know while using [insert medicine]? in the full CMI.

6. Are there any side effects?

Common side effects include: reduced number of blood cells (possible symptoms: fever of 38 °C or above, unusual bruising or bleeding without or on only minor injury, pale skin or lips, tiredness, shortness of breath), bacterial, viral or fungal infections, rash, low blood potassium level in tests, muscle cramps, back pain, swelling of arms and/or legs due to build-up of fluid, weakness, tiredness, feeling generally unwell, fever, diarrhoea, constipation, abdominal pain, nausea, vomiting, cough, shortness of breath, decreased appetite.

Serious side effects that may require urgent medical attention or hospitalization include: serious infections (possible symptoms: fever, chills, sore throat, cough, shortness of breath, nausea, vomiting, diarrhoea), pneumonia (lung infection).

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

▼ This medicine is subject to additional monitoring due to provisional approval. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

MINJUVI®

Active ingredient(s): *tafasitamab*

This medicine has **provisional approval** in Australia in combination with lenalidomide for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) who are not eligible for autologous stem cell transplant (ASCT). The decision to approve this medicine has been made on the basis of promising results from preliminary studies. More evidence is required to be submitted when available to fully confirm the benefit and safety of the medicine for this use.

Consumer Medicine Information (CMI)

This leaflet provides important information about using MINJUVI. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using MINJUVI.**

Where to find information in this leaflet:

1. Why am I using MINJUVI?

MINJUVI contains the active ingredient tafasitamab. MINJUVI is a type of protein called a monoclonal antibody designed to kill cancer cells. This protein acts by attaching to a specific target on the surface of a type of white blood cell called B cells or B lymphocytes. When tafasitamab sticks to the surface of these cells, the cells die.

MINJUVI has provisional approval for the treatment of adult patients with a cancer of B cells called diffuse large B-cell lymphoma. It is used when the cancer has come back after, or not responded to, previous treatment, if patients cannot be treated with a stem cell transplant instead**.**

MINJUVI is used with another cancer medicine lenalidomide at the start of treatment, after which MINJUVI treatment is continued on its own.

The decision to approve this medicine has been made on the basis of promising results from preliminary studies. More evidence is required to be submitted when available to fully confirm the benefit and safety of the medicine for this use.

It is important that you also read the Consumer Medicine Information (CMI) for lenalidomide. Ask your doctor if you have any questions about using lenalidomide.

2. What should I know before I use MINJUVI?

Warnings

Do not use MINJUVI if:

- you are allergic to tafasitamab, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- Have an infection or a history of recurring infections.

You might notice the following during treatment with MINJUVI:

- **Infusion-related reactions**
  Infusion-related reactions may occur most frequently during the first infusion. Your doctor will monitor you for infusion-related reactions during your infusion of MINJUVI. Inform your doctor immediately if you have reactions such as fever, chills, flushing, rash or breathing difficulties within 24 hours of infusion.

  Your doctor will give you treatment before each infusion to reduce the risk of infusion-related reactions. If you do not have reactions, your doctor may decide that you do not need these medicines with later infusions.

- **Reduced number of blood cells**
  Treatment with MINJUVI can severely reduce the number of some types of blood cells in your body, such as white blood cells called neutrophils, platelets and red blood cells. Tell your doctor immediately if you have fever of 38 °C or above, or any signs of bruising or bleeding, as these may be signs of such a reduction.

Your doctor will check your blood cell counts throughout treatment and before starting each treatment cycle.

- **Infections**
  Serious infections, including infections that can cause death, can occur during and following MINJUVI treatment. Tell your doctor if you notice signs of an infection, such as fever of 38 °C or above, chills, cough or pain on urination.

- **Progressive multifocal leukoencephalopathy (PML)**
  PML is a very rare and life threatening infection in the brain. Tell your doctor straight away if you have symptoms such as memory loss, trouble speaking, difficulty walking, or problems with your eyesight.

  If you had any of these symptoms before or during treatment with MINJUVI, or you notice any changes, tell your doctor straight away.

- **Tumour lysis syndrome**
  Some people may develop unusually high levels of some substances (such as potassium and uric acid) in the blood caused by the fast breakdown of cancer cells during treatment. This is called tumour lysis syndrome. Tell your doctor if you have symptoms such as nausea, vomiting, lack of appetite or fatigue, dark urine, decreased urine or side or back pain, muscle cramps, numbness, or heart palpitations. Your doctor may give you treatment before each infusion to reduce the risk of tumour lysis syndrome and perform blood tests to check you for tumour lysis syndrome.

Tell your doctor immediately if you notice any of these problems.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Children and adolescents
MINJUVI is not recommended in children and adolescents under 18 years, as there is no information about the use in this age group.

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Contraception
Use of effective contraception during treatment with MINJUVI and for at least 3 months after end of treatment is recommended for women of childbearing potential.

Pregnancy
Do not use MINJUVI during pregnancy and if you are of childbearing potential not using contraception. Pregnancy must be ruled out before treatment. Tell your doctor immediately if you become pregnant or think you may be pregnant during treatment with MINJUVI.

MINJUVI is given with lenalidomide for up to 12 cycles. **Lenalidomide can harm the unborn baby and must not be used during pregnancy and in women of childbearing potential**, unless all of the conditions of the lenalidomide pregnancy prevention programme are met. Your doctor will provide you with more information and recommendations.

Breast-feeding
Talk to your doctor if you are breastfeeding or intend to breastfeed.

Do not breast-feed during treatment with MINJUVI until at least 3 months after the last dose. It is not known whether tafasitamab passes into breast milk.

MINJUVI contains sodium

This medicine contains 37.0 mg sodium (main component of cooking/table salt) in each dose of 5 vials (the dose of a patient weighing 83 kg). This is equivalent to 1.85% of the recommended maximum daily dietary intake of sodium for an adult.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins, or supplements that you buy without a prescription from your pharmacy, supermarket, or health food shop.

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect MINJUVI.

4. How is MINJUVI given?

MINJUVI is given to you in the hospital or clinic under the supervision of a physician experienced in the use of chemotherapy. Its use should be confined to qualified oncologists or other health professionals specialised in the administration of anti-cancer medicines.

How much is given

The recommended dose is 12 mg tafasitamab per kilogram body weight. The dose you get is based on your weight and will be worked out by your doctor.

In addition, your doctor will prescribe you to take lenalidomide capsules for up to twelve cycles. The recommended starting dose of lenalidomide is 25 mg daily on days 1 to 21 of each cycle.

The doctor adjusts the starting dose and subsequent dosing if needed.

How it is given

MINJUVI will be given into one of your veins via infusion (drip) according to the following schedule:

- Cycle 1: infusion on day 1, 4, 8, 15 and 22 of the cycle
- Cycles 2 and 3: infusion on day 1, 8, 15 and 22 of each cycle
- Cycle 4 and after: infusion on day 1 and 15 of each cycle

During and after the infusion, you will be checked regularly for infusion-related side effects.

How long it will be given for

MINJUVI will be given to you in cycles of 28 days.

After a maximum of twelve cycles of combination therapy, treatment with lenalidomide is stopped. Treatment cycles with MINJUVI alone are then continued until the disease gets worse or you develop unacceptable side effects.

If too much is given (overdose)

As this medicine is being given by your doctor or nurse, it is unlikely that you will be given too much.

In the unlikely event of an overdose, your doctor will monitor you for side effects and treat any symptoms as required.

If you have any further questions on the use of this medicine, ask your doctor.

5. What should I know while using MINJUVI?

During treatment with MINJUVI, you must inform your doctor or nurse if you feel any of the symptoms mentioned under Section 6. Are there any side effects?. Your doctor might reduce or delay the MINJUVI and/or lenalidomide dose, or recommend that you stop treatment, depending on the severity.

Things you must do

- If you are about to be started on any new medicine, remind your doctor that you are being given MINJUVI.
- Remind any doctor, dentist or pharmacist you visit that you are using MINJUVI.
- You should use effective birth control (contraception) during treatment with and for 3 months after your final dose of MINJUVI.
- Tell your doctor or nurse straight away if you experience an allergic reaction or feel unwell during infusion.

Typical symptoms associated with allergic reactions are redness of the face or chest, itching, coughing, shortness of breath, chest discomfort, etc. Other symptoms may occur as well.

These side effects mostly occur during or after the infusion of the first dose. You will be monitored for signs of these effects during and after the infusion.

Call your doctor straight away if you become pregnant while being given this medicine.

Things you must not do

During your treatment with MINJUVI you may feel tired and experience loss of strength. Do not drive or use any tools or machines if you are experiencing any of these side effects.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how MINJUVI affects you.

MINJUVI has no or negligible influence on the ability to drive and use machines. However, fatigue has been reported in patients taking tafasitamab and this should be taken into account when driving or using machines.

Storage

MINJUVI will be stored in the pharmacy or on the ward. The medicine is kept in its original packaging in the refrigerator where the temperature stays between 2 °C and 8 °C.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do

• Rash
• itching
• redness of skin
• hair loss
• abnormal sweating
• low blood potassium level in tests
• decreased appetite
• in blood tests, low blood level of
  - calcium
  - magnesium
• muscle cramps
• back pain
• pain in arms and legs
• muscle and joint pain
• swelling of arms and/or legs due to build-up of fluid
	Speak to your doctor if you have any of these less serious side effects and they worry you.

• weakness, tiredness, feeling generally unwell • fever • inflammation of the membranes lining organs such as the mouth • diarrhoea • constipation • abdominal pain • nausea • vomiting • cough • shortness of breath • worsening of breathing difficulties caused by narrowed lung airways called chronic obstructive pulmonary disease (COPD) • nasal congestion • headache • abnormal sensation of the skin, such as tingling, prickling, numbness • altered sense of taste • infusion-related reactions. These reactions may occur during infusion of MINJUVI or within 24 hours after infusion. Possible symptoms are fever, chills, flushing or breathing difficulties. • decreased weight • in blood tests, increased blood level of C-reactive protein, which could be the result of inflammation or infection • a problem with the immune system called hypogammaglobulinaemia • in blood tests, increased blood level of creatinine, a breakdown product from muscle tissue - liver enzymes: gamma-glutamyltransferase, transaminases - bilirubin, a yellow breakdown substance of the blood pigment	

Serious side effects

Serious side effects	What to do
• reduced number of blood cells - white blood cells, especially a type called neutrophils; possible symptoms: fever of 38 °C or above, or any symptoms of an infection - platelets; possible symptoms: unusual bruising or bleeding without or on only minor injury - red blood cells; possible symptoms: pale skin or lips, tiredness, shortness of breath • lack of certain white blood cells called lymphocytes in blood tests - bacterial, viral or fungal infections, such as respiratory tract infections, bronchitis, lung inflammation, urinary tract infections - serious infections, possible symptoms: fever, chills, sore throat, cough, shortness of breath, nausea, vomiting, diarrhoea. These could be particularly significant if you have been told you have a low level of white blood cells called neutrophils. - pneumonia (lung infection) - sepsis (infection within the bloodstream) • a skin cancer called basal cell carcinoma	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems and to the Sponsor by Email at drugsafety-STA@stbiopharma.com. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What MINJUVI contains

Active ingredient (main ingredient)	Tafasitamab
Other ingredients (inactive ingredients)	Sodium citrate dihydrate Citric acid monohydrate Trehalose dihydrate Polysorbate 20

Do not take this medicine if you are allergic to any of these ingredients.

What MINJUVI looks like

MINJUVI is a powder for solution for intravenous infusion. The powder has a white to slightly yellowish lyophilised powder. (Aust R 387298).

Who distributes MINJUVI

Specialised Therapeutics Alim Pty Ltd
Level 2, 17 Cotham Road, Kew, Victoria 3101

Ph: 1300 798 820
Fax: 1800 798 829
www.stbiopharma.com

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