Package leaflet: Information for the user

MINJUVI 200 mg powder for concentrate for solution for infusion
tafasitamab

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Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What MINJUVI is and what it is used for

What MINJUVI is
MINJUVI contains the active substance tafasitamab. This 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.

What MINJUVI is used for
MINJUVI is used to treat adults 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.

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

2. What you need to know before you use MINJUVI

Do not use MINJUVI

- if you are allergic to tafasitamab or any of the other ingredients of this medicine (listed in section 6)

Warnings and precautions

Talk to your doctor or pharmacist before using MINJUVI 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.
- **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.

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.

Other medicines and MINJUVI
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

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

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

- **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**
  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.

Driving and using machines

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.

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. How to use MINJUVI

A doctor experienced in treating cancer will supervise your treatment. MINJUVI will be given into one of your veins via infusion (drip). During and after the infusion, you will be checked regularly for infusion-related side effects.
MINJUVI will be given to you in cycles of 28 days. The dose you get is based on your weight and will be worked out by your doctor.

The recommended dose is 12 mg tafasitamab per kilogram body weight. This is given as an infusion into a vein 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

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.

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 you have been given more MINJUVI than you should

Because the medicine is given in hospital under a doctor's supervision, this is unlikely. Tell your doctor if you think you may have been given too much MINJUVI.

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

4. Possible side effects

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

Contact your doctor or nurse immediately if you notice any of the following serious side effects – you may need urgent medical treatment. These may be new symptoms or a change in your current symptoms.

- 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)

Other side effects
Tell your doctor or nurse if you notice any of the following side effects:
Very common (may affect more than 1 in 10 people)
- 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
- bacterial, viral or fungal infections, such as respiratory tract infections, bronchitis, lung inflammation, urinary tract 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

Common (may affect up to 1 in 10 people)
- worsening of breathing difficulties caused by narrowed lung airways called chronic obstructive pulmonary disease (COPD)
- headache
- abnormal sensation of the skin, such as tingling, prickling, numbness
- itching
- redness of skin
- 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.
- altered sense of taste
- hair loss
- abnormal sweating
- pain in arms and legs
- muscle and joint pain
- decreased weight
- nasal congestion
- inflammation of the membranes lining organs such as the mouth
- lack of certain white blood cells called lymphocytes in blood tests
- a problem with the immune system called hypogammaglobulinaemia
- in blood tests, low blood level of
  - calcium

  - magnesium
- in blood tests, increased blood level of
  - C-reactive protein, which could be the result of inflammation or infection
  - creatinine, a breakdown product from muscle tissue
  - liver enzymes: gamma-glutamyltransferase, transaminases
  - bilirubin, a yellow breakdown substance of the blood pigment
- a skin cancer called basal cell carcinoma

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system:

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

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

5. How to store MINJUVI

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the vial label and carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2 °C – 8 °C).
Keep the vial in the outer carton in order to protect from light.

Any unused medicine or waste material should be disposed of in accordance with local requirements.

6. Contents of the pack and other information

What MINJUVI contains

- The active substance is tafasitamab. One vial contains 200 mg of tafasitamab. After reconstitution each mL of solution contains 40 mg of tafasitamab.
- The other ingredients are sodium citrate dihydrate, citric acid monohydrate, trehalose dihydrate, polysorbate 20 (see section 2 “MINJUVI contains sodium”).

What MINJUVI looks like and contents of the pack

MINJUVI is a powder for concentrate for solution for infusion. It is a white to slightly yellowish lyophilised powder in a clear glass vial with a rubber stopper, aluminium seal and plastic flip-off cap. Each carton contains 1 vial.

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This leaflet was last revised in 01/2022.

This medicine has been given 'conditional approval'. This means that there is more evidence to come about this medicine.
The Medicines and Healthcare products Regulatory Agency (MHRA) will review new information on this medicine at least every year and this leaflet will be updated as necessary.

Other sources of information
Detailed information on this medicine is available on the Medicines and Healthcare products Regulatory Agency (MHRA) web site: www.mhra.gov.uk

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The following information is intended for healthcare professionals only:

MINJUVI is provided in sterile, preservative-free single-use vials.
MINJUVI should be reconstituted and diluted prior to intravenous infusion.
Use appropriate aseptic technique for reconstitution and dilution.

Instructions for reconstitution
- Determine the dose of tafasitamab based on patient weight by multiplying 12 mg by the patient weight (kg). Then calculate the number of tafasitamab vials needed (each vial contains 200 mg tafasitamab).
- Using a sterile syringe, gently add 5.0 mL sterile water for injections into each MINJUVI vial. Direct the stream toward the walls of each vial and not directly on the lyophilised powder.
- Gently swirl the reconstituted vial(s) to aid the dissolution of the lyophilised powder. Do not shake or swirl vigorously. Do not remove the contents until all of the solids have been completely dissolved. The lyophilised powder should dissolve within 5 minutes.
- The reconstituted solution should appear as a colourless to slightly yellow solution. Before proceeding, ensure there is no particulate matter or discolouration by inspecting visually. If the solution is cloudy, discoloured or contains visible particles, discard the vial(s).

Instructions for dilution
- An infusion bag containing 250 mL sodium chloride 9 mg/mL (0.9%) solution for injection should be used.
- Calculate the total volume of the 40 mg/mL reconstituted tafasitamab solution needed. Withdraw a volume equal to this from the infusion bag and discard the withdrawn volume.
- Withdraw the total calculated volume (mL) of reconstituted tafasitamab solution from the vial(s) and slowly add to the sodium chloride 9 mg/mL (0.9%) infusion bag. Discard any unused portion of tafasitamab remaining in the vial.
- The final concentration of the diluted solution should be between 2 mg/mL to 8 mg/mL of tafasitamab.
- Gently mix the intravenous bag by slowly inverting the bag. Do not shake.

Method of administration
- For the first infusion of cycle 1, the intravenous infusion rate should be 70 mL/h for the first 30 minutes. Afterwards, increase the rate to complete the first infusion within a 2.5-hour period.
- All subsequent infusions should be administered within a 1.5 to 2-hour period.
- Do not co-administer other medicines through the same infusion line.

- Do not administer MINJUVI as an intravenous push or bolus.

Reconstituted solution (prior to dilution)
Chemical and physical in-use stability has been demonstrated for up to 24 hours at 2 °C – 25 °C.

From a microbiological point of view, unless the method of reconstitution precludes the risk of microbial contamination, the reconstituted solution should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

Diluted solution (for infusion)
Chemical and physical in-use stability has been demonstrated for a maximum of 36 hours at 2 °C – 8 °C followed by up to 24 hours at up to 25 °C.

From a microbiological point of view, the diluted solution should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8 °C, unless dilution has taken place in controlled and validated aseptic conditions.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.