PrMINJUVI®
tafasitamab for injection
200 mg/vial

PrMINJUVI® has been issued conditional marketing authorization pending the results of studies to verify its clinical benefit. Patients should be advised of this conditional marketing authorization.

MINJUVI® RECOMMENDED DOSING AND ADMINISTRATION[1]

Guidance for starting patients on MINJUVI®

MINJUVI® (tafasitamab for injection) is indicated in combination with lenalidomide for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (R/R DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma, who are not eligible for autologous stem cell transplant (ASCT).[1]

Incyte

Recommended MINJUVI® + lenalidomide dosing schedule[1]

An IV infusion combined with an oral capsule[1]

MINJUVI® + lenalidomide should be administered for up to 12 cycles (28 days per cycle). Patients should self-administer oral lenalidomide capsules at the **recommended starting dose of 25 mg daily** on days 1 to 21 of each cycle. The starting dose and subsequent dosing should be adjusted, as necessary, according to the lenalidomide Product Monograph.

The **recommended dose is 12 mg MINJUVI®** per kilogram body weight administered as an IV infusion according to the following schedule:

IV: intravenous.

Cycle 1[1]

Days	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
MINJUVI® 12 mg/kg IV infusion	■			■				■							■							■						
Lenalidomide 25 mg capsule	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●							

Cycles 2 and 3[1]

Days	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
MINJUVI® 12 mg/kg IV infusion	■							■							■							■						
Lenalidomide 25 mg capsule	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●							

Cycles 4–12[1]*

Days	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
MINJUVI® 12 mg/kg IV infusion	■														■													
Lenalidomide 25 mg capsule	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●							

Cycles 13+[1]

After a maximum of 12 cycles of combination therapy, stop treatment with lenalidomide and continue to administer MINJUVI® infusions until disease progression or unacceptable toxicity.

Days	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
MINJUVI® 12 mg/kg IV infusion	■														■													

Refer to the MINJUVI® and lenalidomide Product Monographs for more information on recommended doses and dose adjustments.

* Assuming no disease progression or unacceptable toxicity.
IV: intravenous.

MINJUVI® dose considerations and modifications[1]

MINJUVI® must be administered by a healthcare professional experienced in the treatment of cancer patients who has immediate access to emergency equipment and appropriate medical support to manage infusion-related reactions.

Before initiating treatment[1]

Premedications[1]
Administer premedication 30 minutes to 2 hours prior to MINJUVI® infusion to reduce the risk of infusion-related reactions. Premedication may include:

- ☑ Antipyretics
- ☑ Histamine H1 receptor antagonists
- ☑ Histamine H2 receptor antagonists and/or
- ☑ Glucocorticosteroids

For patients who do not experience an infusion-related reaction during the first 3 infusions, premedication is optional for subsequent infusions. If a patient has a Grade 1–3 infusion-related reaction, premedication should be administered before every subsequent infusion.

Treatment of infusion-related reactions[1]

Interrupt infusion immediately if an infusion-related reaction occurs (Grade 2 or higher). In addition, initiate appropriate medical treatment of symptoms.

MINJUVI® dose modifications for adverse reactions[1]

Adverse Reaction	MINJUVI® Dose Modifications
Infusion-related reactions	**Moderate (Grade 2)** • **Interrupt infusion immediately** and manage signs and symptoms. • Once signs and symptoms resolve or reduce to Grade 1, resume infusion at no more than **50%** of the rate at which the reaction occurred. If the patient does not experience further reaction within 1 hour and vital signs are stable, the infusion rate may be increased every 30 minutes as tolerated to the rate at which the reaction occurred. **Severe (Grade 3)** • **Interrupt infusion immediately** and manage signs and symptoms. • Once signs and symptoms resolve or reduce to Grade 1, resume infusion at no more than **25%** of the rate at which the reaction occurred. If the patient does not experience further reaction within 1 hour and vital signs are stable, the infusion rate may be increased every 30 minutes as tolerated to a maximum of **50%** of the rate at which the reaction occurred. • If after rechallenge the reaction returns, **stop the infusion immediately.** **Life-threatening (Grade 4)** • **Stop the infusion immediately**, manage signs and symptoms, and permanently discontinue MINJUVI®.
Myelosuppression	**Thrombocytopenia:** platelet count <50,000 mcL • **Withhold MINJUVI® and lenalidomide** and monitor CBC weekly until platelet count is ≥50,000/mcL. • When platelet count recovers to at least 50,000/mcL, resume MINJUVI® at the same dose and lenalidomide at a reduced dose. **Neutropenia:** neutrophil count <1,000/mcL for at least 7 days **OR** neutrophil count 1,000/mcL or less with an increase of body temperature to 38°C or higher **OR** neutrophil count <500/mcL • **Withhold MINJUVI® and lenalidomide** and monitor CBC weekly until neutrophil count is ≥1,000/mcL. • When neutrophil count recovers to at least 1,000/mcL, resume MINJUVI® at the same dose and lenalidomide at a reduced dose.

Adapted from the MINJUVI® Product Monograph.[1]
mcL: microliters; CBC: complete blood count.

Refer to the lenalidomide Product Monograph for additional guidance on dosage modifications.

Dose modifications for renal or hepatic impairment[1]

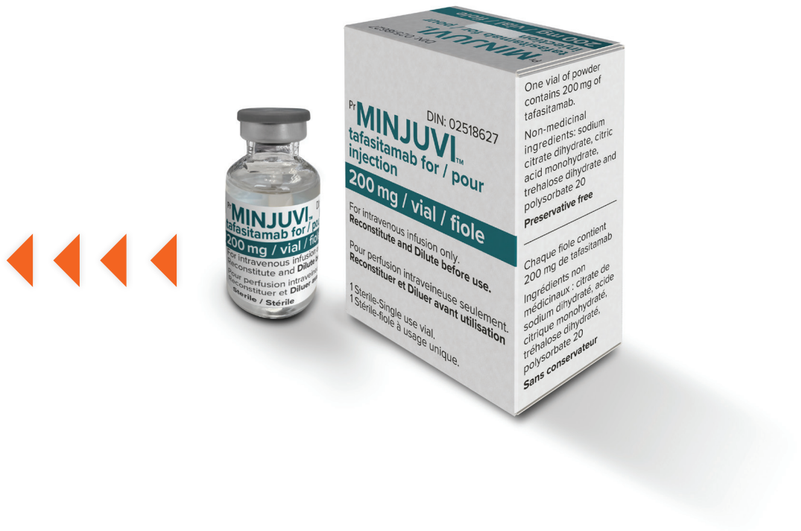
No MINJUVI® dose modifications are needed for patients with mild or moderate renal impairment. However, the effect of severe renal impairment to end-stage renal disease (CrCl <30 mL/min) is unknown.

No MINJUVI® dose modifications are needed for patients with mild hepatic impairment. The effect of moderate to severe hepatic impairment (total bilirubin >1.5 times ULN and any AST) is unknown.

CrCl: creatinine clearance; ULN: upper limit of normal; AST: aspartate aminotransferase.

MINJUVI® 6-step reconstitution process[1]

MINJUVI® is provided in sterile, preservative-free, single-use 200 mg vials. MINJUVI® should be reconstituted and diluted prior to IV infusion. Use appropriate aseptic technique for reconstitution and dilution.[1]



1. Determine the dose of MINJUVI® based on the patient's weight prior to each cycle:
   12 mg/kg MINJUVI® × patient's weight (kg) = MINJUVI® dose per infusion (mg)
2. Calculate the number of MINJUVI® vials needed (each vial contains 200 mg of tafasitamab).
3. Using a sterile syringe, gently add 5 mL sterile water for injection into each tafasitamab vial. Direct the stream toward the walls of each vial and not directly on the lyophilized powder. The resulting solution contains MINJUVI® at a concentration of 40 mg/mL.
4. Gently swirl the reconstituted vial(s) to aid the dissolution of the lyophilized powder. Do not shake or swirl vigorously. Do not remove the contents until all of the solids have been completely dissolved. The lyophilized powder should completely dissolve within 5 minutes.
5. The reconstituted MINJUVI® solution should appear as a colourless to slightly yellow solution. Before proceeding, ensure there is no particulate matter or discolouration by visually inspecting the vials. If the solution is cloudy, discoloured or contains visible particles, discard the vial(s) and prepare freshly reconstituted MINJUVI®.
6. The reconstituted MINJUVI® solution contains no preservative and should be used as soon as possible after reconstitution. If not used immediately, the reconstituted product may be stored prior to dilution for up to 30 days at 2°C–8°C or up to 24 hours at 25°C. Do not freeze or shake. Protect from light during storage.

IV: intravenous.

MINJUVI® 5-step dilution process[1]

1. Obtain a 250 mL sodium chloride 9 mg/mL (0.9%) solution infusion bag for injection.
2. Calculate the total volume of the 40 mg/mL reconstituted MINJUVI® solution needed based on the patient's weight prior to each cycle.

$$\text{Volume} = \frac{\text{12 mg/kg MINJUVI® × patient's weight (kg)}}{\text{Reconstituted vial concentration (40 mg/mL)}}$$

3. Withdraw saline solution equal to the calculated volume from the infusion bag and discard the withdrawn volume.
4. Withdraw the total calculated volume (mL) of the reconstituted MINJUVI® solution from the vial and slowly add to the sodium chloride infusion bag. Discard any unused portion of MINJUVI® solution remaining in the vial.
5. The final concentration of the diluted solution should be between 2–8 mg/mL of MINJUVI®. Gently mix the IV bag by inverting the bag slowly. **Do not shake**.

IV: intravenous.

After dilution:[1]

Once diluted, the product should be used immediately.

If not used immediately, the infusion solution may be stored for a maximum of 14 days at 2°C–8°C followed by up to 24 hours at up to 25°C.

Do not freeze.

Do not shake.

Protect from light during storage.

MINJUVI® + lenalidomide administration[1]*

Administer MINJUVI® as an IV infusion.
Do not administer as an IV push or bolus.[1]

Recommended supplies:[1]

1. 250 mL 0.9% NaCl infusion bag or bottle
2. Standard IV infusion administration set
3. 0.2 µm in-line filter

Administer MINJUVI® as an IV infusion after reconstitution and dilution.

For the **first infusion** of cycle 1, the IV infusion **rate should be 70 mL/h** for the first 30 minutes. Afterwards, increase the rate so that the first infusion is complete within a 2.5-hour period.

Monitor patients during the entire infusion for infusion-related reactions. Most infusion-related reactions occur in the first 15 minutes of the first dose.

Follow standard care measures for monitoring after the infusion is complete. Advise patients to contact their healthcare professional if they experience signs and symptoms of infusion-related reactions including fever, chills, rash or breathing problems within 24 hours of infusion.

IV: intravenous.

In the absence of any prior infusion-related reaction, **subsequent infusions** may be administered within a **1.5–2-hour period**.

Do not co-administer other medicines through the same infusion line.

After the infusion is complete, flush the tubing with 0.9% NaCl injection to **ensure the entire dose is administered**.

Scan the QR code below to access the lenalidomide Product Monograph for more information on recommended dose and dose adjustments.

* No incompatibilities have been observed between MINJUVI® with infusion containers made of polypropylene, PVC, polyethylene, polyethylenterephthalate, or glass and infusion sets made of polyurethane or PVC. No incompatibilities were observed with terminal in-line filters with neutral or positively charged polyethersulfone membrane, 0.2 µm.

PVC: polyvinylchloride.

Questions your patients may ask about their MINJUVI® dosage and administration[1,2]

Why am I administered medication before my MINJUVI® infusions?

Premedications are administered prior to MINJUVI® infusions to reduce the risk of infusion-related reactions. Some possible premedications may include: antipyretics, histamine H1 receptor antagonists, histamine H2 receptor antagonists, and/or glucocortisteroids.

Why did I receive premedication for my first 3 infusions, but not for my 4th?

If you did not experience an infusion-related reaction during the first 3 infusions, premedication is optional for subsequent infusions.

How long will my MINJUVI® infusions take?

The first infusion should be complete within a 2.5-hour period. If there are no infusion-related reactions, subsequent infusions may take between 1.5 to 2 hours.

Can I start my MINJUVI® treatment if I have recently received a vaccine?

The safety of immunization with live vaccines following MINJUVI® therapy has not been investigated, and vaccination with live vaccines is not recommended concurrently with MINJUVI® therapy.

Potential questions about lenalidomide[1,2]

Can I start my MINJUVI® and lenalidomide treatments at different times?

It is important to start your MINJUVI® and lenalidomide treatments on the same day.

Does it matter what time I take my lenalidomide capsule(s)?

You should orally take lenalidomide capsule(s) at about the same time each day.

When should I stop taking my lenalidomide capsule?

After a maximum of 12 cycles of MINJUVI® and lenalidomide, MINJUVI® will be administered alone.

Potential questions about dosing schedule[1]

How can I track my appointments?

You can use the treatment tracker in the provided MINJUVI® patient brochure to track your appointments.

Where will I receive my MINJUVI® infusions?

You will be able to receive your MINJUVI® infusions at a hospital or an infusion clinic from a healthcare professional experienced in the treatment of cancer patients. You may be eligible to access the private infusion clinics offered by the Incyte Solutions™ Support Program.

Provide your patients with tips to manage their treatment

Help patients remember their treatments by suggesting:

- Using the appointment tracker in the MINJUVI® patient brochure
- Setting a reminder on their phone
- Combining taking their lenalidomide capsule with other daily routines (e.g., brushing their teeth, meals)
- Using a pill box designated only for lenalidomide

The Incyte Solutions™ Support Program

At Incyte Biosciences Canada, we want to help provide support for patients. That is why Incyte Solutions™ is available to provide resources for patients who have been prescribed MINJUVI®.

Through this program, patients have direct access to additional support to help them throughout treatment. Incyte Solutions™ also offers private infusion clinics for select MINJUVI® patients.

Incyte Solutions™ SUPPORT PROGRAM

Phone: **1-84-INCYTE-00** (1-844-629-8300)
Email: **support@incytesolutions.ca**
Fax: **1-84-INCYTE-01** (1-844-629-8301)

MINJUVI® safety information[1]

Indication and clinical use:

MINJUVI® (tafasitamab for injection) is indicated in combination with lenalidomide for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (R/R DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma, who are not eligible for autologous stem cell transplant (ASCT).

Authorization was based on overall response rate, complete response rate and durability of response from a single-arm clinical study. An improvement in progression-free survival or overall survival has not been established.

Pediatrics (<18 years of age): No data are available to Health Canada; therefore, Health Canada has not authorized an indication for pediatric use.

Geriatrics (≥65 years of age): Among 81 patients treated in the L-MIND study, 72% were 65 years and older. Patients 65 years of age and older had more serious treatment emergent adverse events (TEAEs) (57%) than younger patients (39%).

Evidence from clinical studies does not suggest that use in the geriatric population is associated with differences in effectiveness.

Contraindications:

- MINJUVI® is contraindicated in patients who are hypersensitive to this drug or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container.

Most serious warnings and precautions:

Infection: Clinically significant and/or life-threatening adverse events including fatal, life-threatening, or serious infections, including opportunistic infections have been reported in patients treated with MINJUVI® in combination with lenalidomide.

Myelosuppression: Serious and severe myelosuppression, including neutropenia, febrile neutropenia, thrombocytopenia, and anemia have been reported in patients treated with MINJUVI® in combination with lenalidomide.

Progressive Multifocal Leukoencephalopathy (PML): PML can occur in patients receiving MINJUVI® in combination with lenalidomide. MINJUVI® treatment should be interrupted in case of PML suspicion, until the diagnosis can be clearly established. Discontinue MINJUVI® therapy and consider discontinuation or reduction of lenalidomide therapy in patients who develop PML.

Hepatitis B Virus (HBV) Reactivation: HBV reactivation has been observed in studies of MINJUVI® in combination with lenalidomide. Patients should be screened for HBV infection before treatment initiation and should be monitored during and after treatment with MINJUVI®. In the event of HBV reactivation, MINJUVI® should be discontinued.

Other relevant warnings and precautions:

- MINJUVI® is administered by intravenous infusion only. DO NOT administer as an intravenous push or bolus dose.
- Infusion-related reactions may occur and have been reported in clinical studies with MINJUVI®.
- Patients should be monitored closely throughout the infusion.
- Patients should be monitored closely for tumor lysis syndrome during treatment. Patients with high tumor burden and rapidly proliferative tumor may be at increased risk of tumor lysis syndrome.
- Vaccination with live vaccines is not recommended concurrently with MINJUVI® therapy.
- Treatment with tafasitamab in combination with lenalidomide should not be initiated in female patients unless pregnancy has been excluded.
- MINJUVI® may cause fetal harm. Advise females of reproductive potential to use effective contraception during MINJUVI® treatment and for at least 3 months after the end of treatment.
- MINJUVI® is not recommended during pregnancy and in women of childbearing potential not using contraception.
- Advise women not to breast-feed during treatment with MINJUVI® until at least 3 months after the last dose.

For more information:

Please consult the Product Monograph at pdf.hres.ca/dpd_pm/00080648.PDF for important information relating to monitoring and laboratory tests, adverse reactions, drug interactions, and dosing information which have not been discussed in this piece. The Product Monograph is also available by calling 1-833-309-2759 or contacting medinfocanada@incyte.com.

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Visit our resource hub for additional resources and information on how to enroll your patients in the Incyte Solutions™ Support Program: **www.IncyteOnco.ca.**

Incyte Solutions™
SUPPORT PROGRAM

Phone: **1-84-INCYTE-00** (1-844-629-8300)
Email: **support@incytesolutions.ca**
Fax: **1-84-INCYTE-01** (1-844-629-8301)

References:

1. MINJUVI® Product Monograph. Incyte Corporation. May 21, 2025. **2.** PrREVLIMID® Product Monograph. Celgene Corporation. February 9, 2024.

REVIEWED BY PAAB

MEMBER OF INNOVATIVE MEDICINES CANADA

Incyte