

Pr
MINJUVI®
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.

KEEP MINJUVI® IN MIND

Consider MINJUVI® for your R/R DLBCL not otherwise specified patients who are not eligible for ASCT^{1,2}

MINJUVI® (tafasitamab for injection) is indicated in combination with lenalidomide for the treatment of adult patients with R/R DLBCL not otherwise specified, including DLBCL arising from low grade lymphoma, who are not eligible for ASCT.¹

Available in Canada since 2021. As of 2024, MINJUVI® has been available in a total of 45 countries. In the United States, over 4,000 patients have been treated with MINJUVI®.^{1,3*}

* Clinical significance is unknown.

R/R: relapsed or refractory; DLBCL: diffuse large B-cell lymphoma; ASCT: autologous stem cell transplant.



R/R DLBCL

MOA

L-MIND
Study

Efficacy
data

Safety
profile

Dosage &
administration

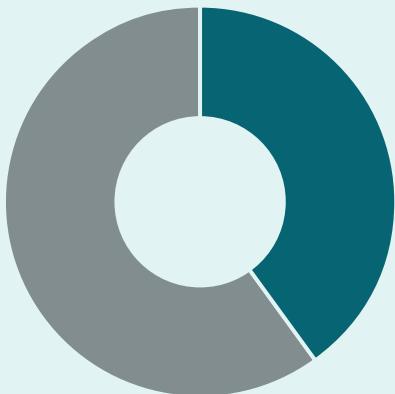
Incyte
Solutions™

Safety
information



R/R DLBCL not otherwise specified is an aggressive cancer⁴

30%–40% of patients
with DLBCL will either be
refractory to or relapse
following frontline therapy.⁵



Some patients with R/R DLBCL not otherwise specified are **ineligible for ASCT**⁵

Consider MINJUVI® for your patients with R/R DLBCL not otherwise specified who are not eligible for ASCT.¹

NCCN Guideline recommendations²

For patients with no intention to proceed to transplant

**Relapsed disease
>12 months**

Clinical trial

OR

Second-line therapy
(see next page)

OR

Palliative ISRT

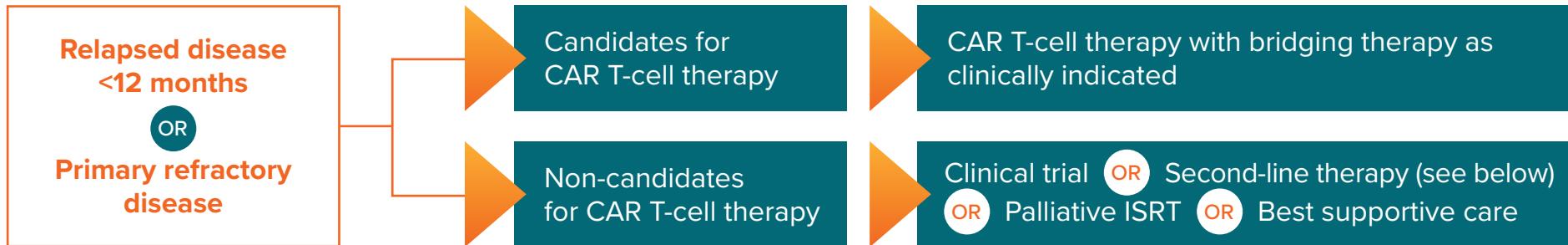
OR

Best
supportive care

Adapted from NCCN Guidelines.²

R/R: relapsed or refractory; DLBCL: diffuse large B-cell lymphoma; ASCT: autologous stem cell transplant; ISRT: involved-site radiation therapy; NCCN: National Comprehensive Cancer Network.





Adapted from NCCN Guidelines.²

Second-line therapy options²

Preferred second-line therapy regimens (in alphabetical order):

- CAR T-cell therapy (CD19-directed) (if eligible)
 - Lisocabtagene maraleucel
- Polatuzumab vedotin ± bendamustine ± rituximab
- Tafasitamab + lenalidomide

Other recommended regimens (in alphabetical order):

- CEOP ± rituximab
- DA-EPOCH ± rituximab
- GDP ± rituximab or (gemcitabine, dexamethasone, carboplatin) ± rituximab
- GemOx ± rituximab
- Rituximab

Useful in certain circumstances:

- Brentuximab vedotin for CD30+ disease
- Ibrutinib (non-GCB DLBCL)
- Lenalidomide ± rituximab (non-GCB DLBCL)

Please refer to the NCCN Guidelines for more information on bridging therapy options for the CAR T-cell therapy candidates as well as second-line therapy options.

CAR: chimeric antigen receptor; ISRT: involved-site radiation therapy; NCCN: National Comprehensive Cancer Network; R/R: relapsed or refractory; DLBCL: diffuse large B-cell lymphoma; ASCT: autologous stem cell transplant; CEOP: cyclophosphamide, etoposide, vincristine, prednisone; DA-EPOCH: dose-adjusted etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin; GDP: gemcitabine, dexamethasone, cisplatin; GemOx: gemcitabine, oxaliplatin; GCB: germinal center B-cell.

MINJUVI®: An anti-CD19 mAb^{1,2*}



CD19 is expressed on the surface of both pre-B and mature B lymphocytes as well as on several B-cell malignancies, including DLBCL^{1†}

MINJUVI® (tafasitamab) is an Fc-enhanced mAb that **targets the CD19 antigen**. Upon binding to CD19, MINJUVI® mediates B-cell lysis through¹

► Immune effector mechanisms, including **ADCC** and **ADCP** ► **Apoptosis**

The combination of MINJUVI® + lenalidomide¹

In *in vitro* laboratory studies conducted in DLBCL tumour cell lines, the combination of **MINJUVI® + lenalidomide was associated with greater cytotoxicity** than observed when cells were treated with either agent alone.¹

R/R DLBCL

MOA

L-MIND Study

Efficacy data

Safety profile

Dosage & administration

Intrate Solutions™

Safety information

* Clinical significance is unknown.

† MINJUVI® (tafasitamab for injection) is indicated in combination with lenalidomide for the treatment of adult patients with R/R DLBCL not otherwise specified, including DLBCL arising from low grade lymphoma, who are not eligible for ASCT.

mAb: monoclonal antibody; DLBCL: diffuse large B-cell lymphoma; Fc: fragment crystallizable; ADCC: antibody-dependent cellular cytotoxicity; ADCP: antibody-dependent cellular phagocytosis; R/R: relapsed or refractory; ASCT: autologous stem cell transplant.

Binding of MINJUVI® to CD19 mediates B-cell lysis through apoptosis and immune effector mechanisms¹

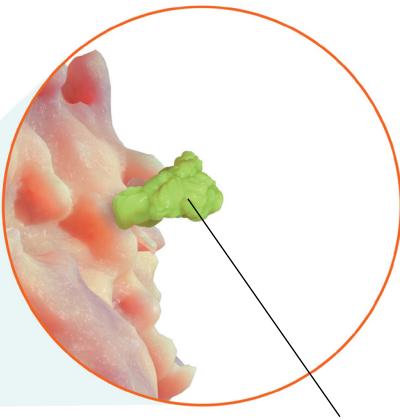
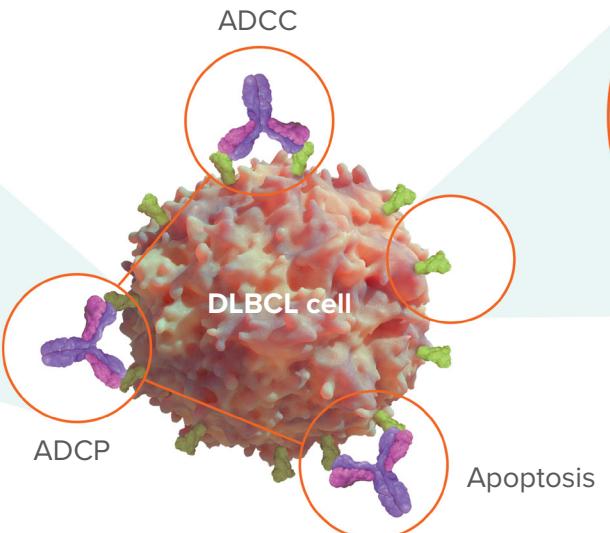
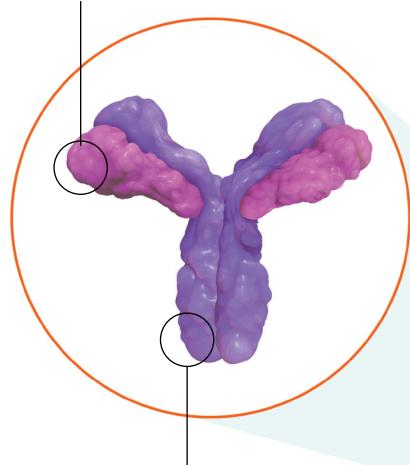


Mechanism of action (MOA)^{1,6}

MINJUVI® (Fc-enhanced, anti-CD19 mAb)

- ADCC
- ADCP
- Apoptosis

CD19 binding site



Adapted from the MINJUVI® Product Monograph and Salles *et al.* 2021.^{1,6}

Fc: fragment crystallizable; mAb: monoclonal antibody; ADCC: antibody-dependent cellular cytotoxicity; ADCP: antibody-dependent cellular phagocytosis; DLBCL: diffuse large B-cell lymphoma.

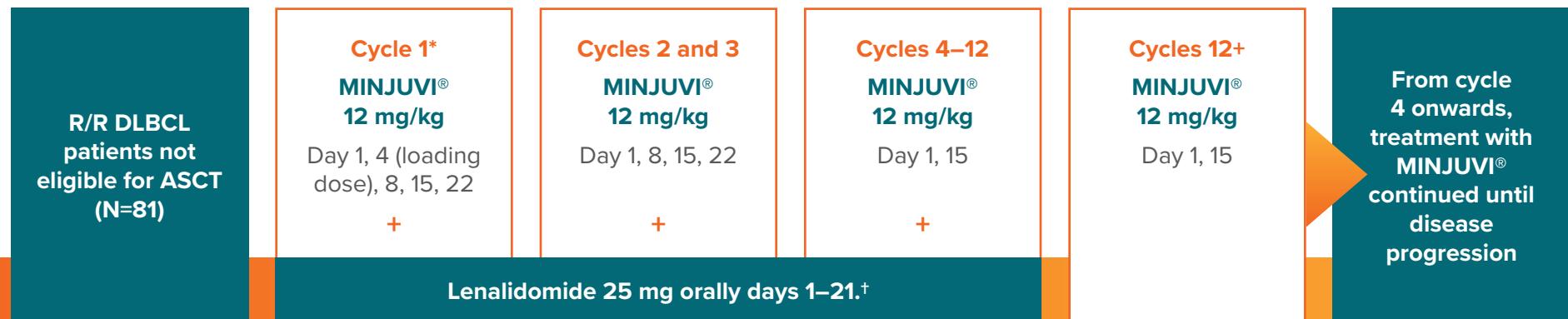
The L-MIND study design¹



L-MIND: An open-label, prospective, multicentre, single-arm, phase 2 study^{1,7}

MINJUVI® + lenalidomide followed by **MINJUVI® monotherapy** was studied in L-MIND¹

- The median duration of exposure to MINJUVI® and lenalidomide was 6.7 months.
- 26 (36.6%) patients completed 12 cycles of MINJUVI®. 23 (32.4%) patients completed 12 cycles of lenalidomide.¹



Primary efficacy endpoint¹

- **Best ORR** (defined as the sum of the proportions of patients who were complete or partial responders as assessed by an IRC who applied the IWGRC)

Additional endpoints¹

- **DoR:**
 - in patients achieving CR+PR (overall DoR);
 - in patients with CR as best response;
 - and in patients with PR as best response.

Premedication, including antipyretics, histamine H1 and H2 receptor blockers and glucocorticosteroids, was given 30 to 120 minutes prior to the first three MINJUVI® infusions.¹

^{*} Each cycle was 28 days long.

[†] Patients self-administered 25 mg lenalidomide capsules.

R/R: relapsed or refractory; DLBCL: diffuse large B-cell lymphoma; ASCT: autologous stem cell transplant; ORR: overall response rate; IRC: independent review committee; IWGRC: International Working Group Response Criteria; DoR: duration of response; CR: complete response; PR: partial response.

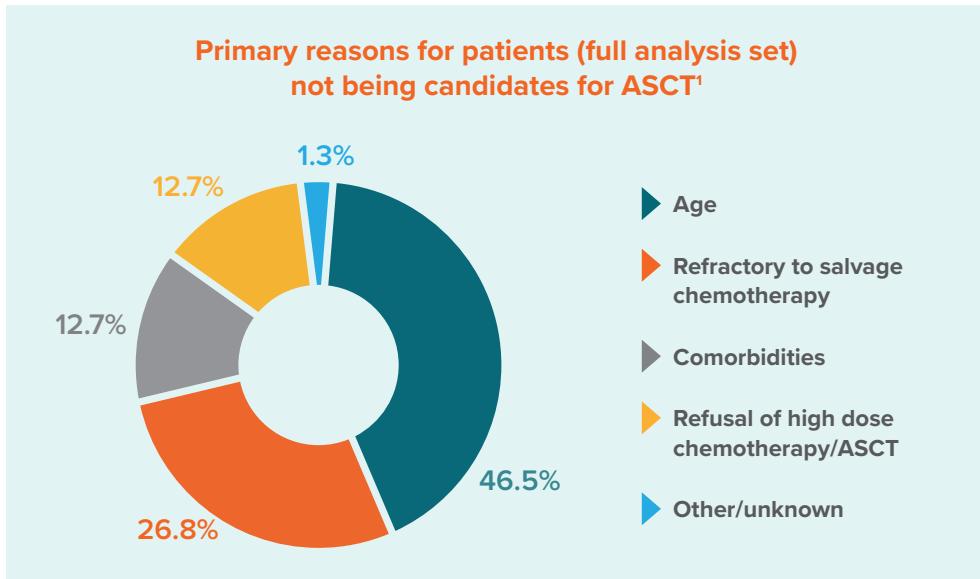


Key eligibility criteria:^{1,7*†}

- ▶ Adult patients that had R/R DLBCL
 - Until a protocol amendment introduced on June 27, 2016, only patients whose disease relapsed within 3 months of a previous anti-CD20-containing regimen were defined as **primary refractory** and excluded. Therefore, patients with disease that relapsed or progressed between 3 and 6 months of first-line therapy were recruited before this amendment and considered as primary refractory patients (as per the NCCN Guidelines).
- ▶ Patients had received 1–3 prior systemic DLBCL therapies
- ▶ Patients were not candidates for high dose chemotherapy followed by ASCT at the time of the trial
- ▶ At least one of the prior systemic therapies had to include a CD20 targeted therapy

Additional patient demographics:^{1,7}

- ▶ 71 of the enrolled patients had DLBCL (confirmed by a central laboratory) and received combination treatment on study
- ▶ Median age: 71 years (range: 41–86 years)
- ▶ 87% were white; 55% were male
- ▶ Median number of prior therapies: 2
- ▶ All patients had received a prior CD20-containing therapy
- ▶ 14 patients (19.7%) had primary refractory disease
- ▶ 32 (45.1%) were refractory to their last prior therapy and 30 (42.3%) were refractory to rituximab
- ▶ 9 patients (12.7%) had received prior ASCT



* Refer to the L-MIND clinical trial article (Salles *et al.*, 2020) for more information.

† Patients were not eligible if they had other types of lymphoma, including PMBCL or Burkitt lymphoma or if they had a history of double/triple hit genetics (i.e., detection of MYC with BCL2 and/or BCL6 translocations). Patients with a history of CNS lymphoma involvement were also excluded.

R/R: relapsed or refractory; DLBCL: diffuse large B-cell lymphoma; NCCN: National Comprehensive Cancer Network; ASCT: autologous stem cell transplant; PMBCL: primary mediastinal B-cell lymphoma; CNS: central nervous system.

Observed responses in L-MIND¹



R/R DLBCL

MOA

L-MIND
Study

Efficacy
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Safety
profile

Dosage &
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Injute
Solutions™

Safety
information

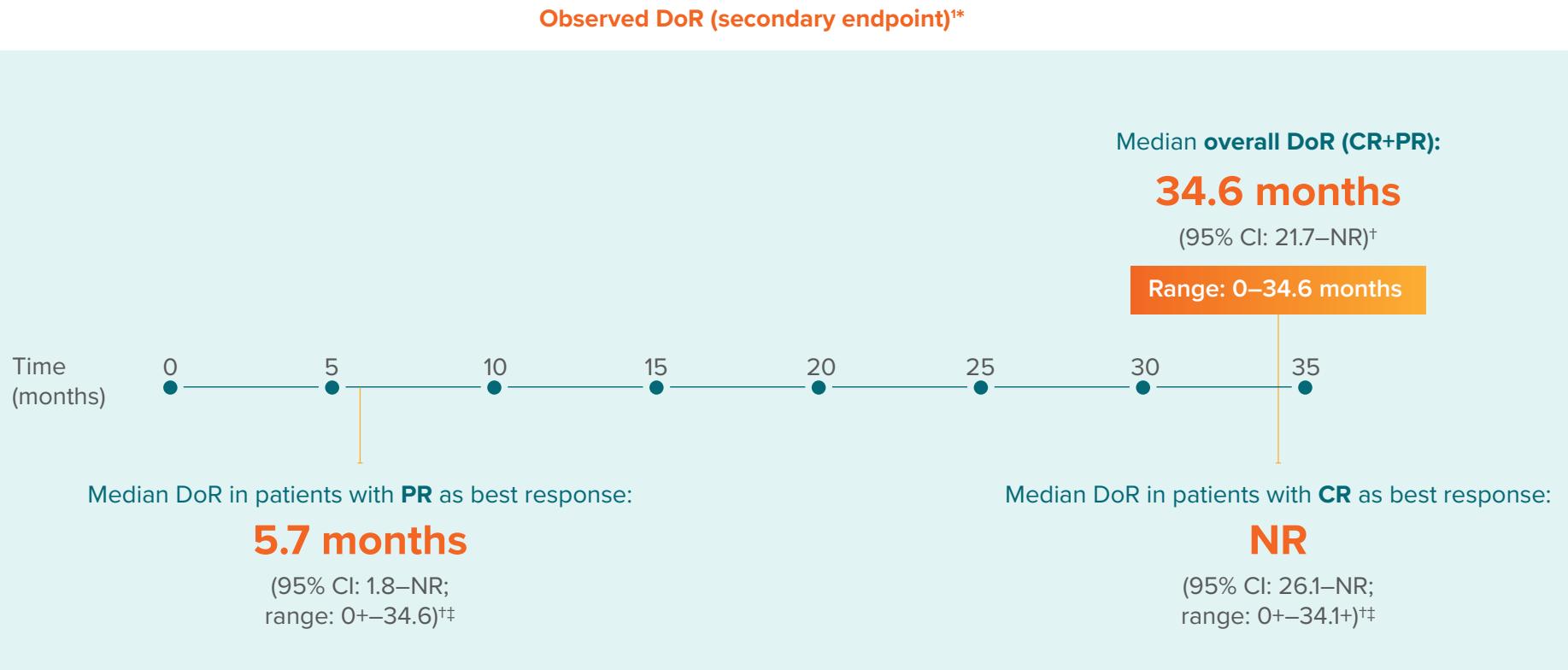
Best objective response rate (N=71)^{1*†}



* Refer to the L-MIND clinical trial article (Salles *et al.*, 2020) for more information.

† CI based on the Clopper-Pearson method.

PR: partial response; CI: confidence interval; CR: complete response; ORR: overall response rate.



To learn more about MINJUVI® and the L-MIND clinical trial, contact your **Incyte representative**.

* Refer to the L-MIND clinical trial article (Salles *et al.*, 2020) for more information.

† Kaplan-Meier estimates. CI based on the Brookmeyer and Crowley method.

‡ + denotes a censored observation.

DoR: duration of response; CR: complete response; PR: partial response; CI: confidence interval; NR: not reached.

MINJUVI® demonstrated a generally well-tolerated safety profile¹



Adverse reactions (≥10%) in patients with R/R DLBCL who received MINJUVI® in L-MIND¹

Adverse Reaction	MINJUVI® (N=81)	
	All Grades n (%)	Grade 3 or 4 n (%)
Blood and lymphatic system disorders		
Neutropenia	41 (51)	40 (49)
Anemia	29 (36)	6 (7)
Thrombocytopenia	25 (31)	14 (17)
Leukopenia	12 (15)	9 (11)
Febrile neutropenia	10 (12)	10 (12)
General disorders and administration site conditions		
Asthenia*	32 (39.5)	3 (3.7)
Pyrexia	19 (24)	1 (1.2)
Peripheral edema	19 (24)	0
Gastrointestinal disorders		
Diarrhea	29 (36)	1 (1.2)
Constipation	14 (17)	0
Nausea	12 (15)	0
Vomiting	12 (15)	0

Adapted from the MINJUVI® Product Monograph.¹

* Includes fatigue and malaise.

R/R: relapsed or refractory; DLBCL: diffuse large B-cell lymphoma.



Adverse reactions (≥10%) in patients with R/R DLBCL who received MINJUVI® in L-MIND¹

Adverse Reaction	MINJUVI® (N=81)	
	All Grades n (%)	Grade 3 or 4 n (%)
Respiratory, thoracic and mediastinal disorders		
Cough	21 (26)	1 (1.2)
Dyspnea	10 (12)	1 (1.2)
Infections		
Respiratory tract infection*	43 (53.1)	11 (13.6)
Urinary tract infection†	14 (17)	4 (4.9)
Metabolism and nutrition disorders		
Decreased appetite	18 (22)	0
Hypokalemia	15 (19)	5 (6)
Musculoskeletal and connective tissue disorders		
Back pain	15 (19)	2 (2.5)
Muscle spasms	12 (15)	0
Skin and subcutaneous tissue disorders		
Rash‡	13 (16)	2 (2.5)

Adapted from the MINJUVI® Product Monograph.¹

* Respiratory tract infection includes bronchitis, bronchopulmonary aspergillosis, influenza, lower respiratory tract infection, nasopharyngitis, parainfluenzae virus infection, pharyngitis, pharyngitis streptococcal, pneumonia, respiratory syncytial virus infection, respiratory tract infection, rhinitis, sinusitis, tonsillitis, upper respiratory tract infection, upper respiratory tract infection bacterial, viral pharyngitis.

† Urinary tract infection includes: urinary tract infection, Escherichia urinary tract infection, urinary tract infection bacterial, and urinary tract infection enterococcal.

‡ Rash includes rash, rash maculopapular, rash pruritus, rash erythematous.

R/R: relapsed or refractory; DLBCL: diffuse large B-cell lymphoma.



MINJUVI® demonstrated a generally well-tolerated safety profile¹ (cont'd)

Serious adverse events occurred in 52% of patients who received MINJUVI®. Serious adverse events in ≥6% of patients included infections (26%) including pneumonia (7%), and febrile neutropenia (6%).¹

Fatal adverse events occurred in 5% of patients who received MINJUVI®, including:

- ▶ Cerebrovascular accident (1.2%)
- ▶ Respiratory failure (1.2%)
- ▶ Progressive multifocal leukoencephalopathy (1.2%)
- ▶ Sudden death (1.2%)

Permanent discontinuation of MINJUVI® or lenalidomide due to an adverse event occurred in 25% of patients and permanent discontinuation of MINJUVI® due to an adverse event occurred in 15%. The most frequent adverse event which resulted in permanent discontinuation of MINJUVI® were infections (5%), nervous system disorders (2.5%), respiratory, thoracic and mediastinal disorders (2.5%).¹

In patients treated with MINJUVI® + lenalidomide, ≥Grade 3 hematological adverse reactions (in 59% of patients) included neutropenia (49%), thrombocytopenia (17%), febrile neutropenia (12%), leukopenia and anemia (7%). Grade 4 hematological adverse reactions (in 31% of patients) included neutropenia (including agranulocytosis), thrombocytopenia, febrile neutropenia, and leukopenia.

The incidences of hematological events decreased by at least 20% for neutropenia, anemia and thrombocytopenia when patients were switched from the combination therapy phase to MINJUVI® alone.

No incidences of febrile neutropenia were reported with MINJUVI® monotherapy.

Recommended dosing schedule for MINJUVI® + lenalidomide¹

An IV infusion combined with an oral capsule¹

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

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 schedule on the following page.

Recommended premedications¹

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.¹

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



Recommended dosing schedule for MINJUVI® + lenalidomide¹ (cont'd)



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	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●						

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.

CYCLES 13+ 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																												

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.



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, eligible patients may have access to financial assistance and additional support to help them throughout treatment. Incyte Solutions™ also offers private infusion clinics for select MINJUVI® patients. The Program will collect, use, disclose and store patient information to provide the following services:

- Nursing and/or pharmacists' support
- Assessment of eligibility to financial assistance
- Assistance in communicating with drug plan administrators, managers or insurance companies to aid in securing reimbursement coverage for the patient's prescription
- Reporting on the patient's insurance coverage to the prescribing healthcare professional (HCP)
- Regular communications on the patient's therapy and support program offerings, where applicable
- Other services as offered from time to time.

MINJUVI® can be administered in a healthcare setting, such as a hospital or private infusion clinic. There are over 100 private infusion clinics in Canada – find a clinic at bioscript.ca/en-CA.



MINJUVI® + lenalidomide — **reimbursed in Quebec** since 2023 (criteria apply).^{8,9*}

* RAMQ Liste des médicaments – Établissements: tafasitamab (MINJUVI®) in combination with lenalidomide, for the treatment of adults with R/R DLBCL not otherwise specified, including DLBCL arising from low-grade lymphoma, who are not eligible for ASCT. Patients must also meet the following criteria: be anti-CD19 therapy-naïve and have an ECOG performance status of 0 to 2. The duration of each authorization is 4 months. Tafasitamab is administered at a dose of 12 mg/kg, in cycles of 28 days, on days 1, 4, 8, 15 and 22 of the first cycle, on days 1, 8, 15 and 22 of the second and third cycles, and on days 1 and 15 of subsequent cycles. When requesting continuation of treatment, the physician must provide proof of a beneficial clinical effect by the absence of disease progression. RAMQ is the Official Mark of the Régie de l'assurance maladie du Québec (RAMQ).

ECOG: Eastern Cooperative Oncology Group.

MINJUVI® safety information¹



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.

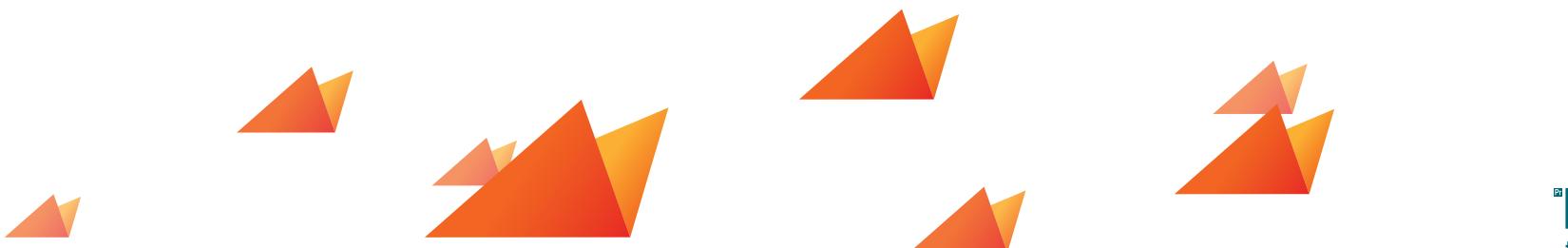
For more information:

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.

References



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MINJUVI®
tafasitamab for injection

KEEP MINJUVI® IN MIND

Consider MINJUVI® for your R/R DLBCL not otherwise specified patients who are not eligible for ASCT^{1,2}

- MINJUVI® + lenalidomide observed responses in L-MIND
 - 38 patients (53.5%) achieved ORR (95% CI: 41.3–65.5).^{1†}
 - Median overall DoR (CR+PR): 34.6 months (95% CI: 21.7–NR; range: 0–34.6 months)^{1‡}
- MINJUVI® + lenalidomide demonstrated a generally well-tolerated safety profile¹
 - The most common adverse reactions (≥35%; all Grades) were neutropenia (41/81; 51%), anemia (29/81; 36%), asthenia (32/81; 39.5%), diarrhea (29/81; 36%), and respiratory tract infection (43/81; 53.1%)

An anti-CD19 mAb^{1,2*}

Available in Canada since 2021. As of 2024, MINJUVI® has been available in a total of 45 countries. In the United States, over 4,000 patients have been treated with MINJUVI®.^{1,3*}

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



To learn more about MINJUVI® and the L-MIND clinical trial, contact your **Incyte representative**.

* Clinical significance is unknown.

† CI based on the Clopper-Pearson method.

‡ Kaplan-Meier estimates. CI based on the Brookmeyer and Crowley method.

mAb: monoclonal antibody; R/R: relapsed or refractory; DLBCL: diffuse large B-cell lymphoma; ORR: overall response rate; CI: confidence interval; DoR: duration of response; CR: complete response; PR: partial response; NR: not reached.



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MINJUVI®
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200 mg/vial

R/R DLBCL

MOA

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Safety
information