Not an actual patient or healthcare provider.

MONJUVI®
tafasitamab-cxix | 200 mg
for injection, for intravenous use

YOUR GUIDE TO DOSAGE & ADMINISTRATION

INDICATIONS & USAGE

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

This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) recommend tafasitamab-cxix (MONJUVI) in combination with lenalidomide as a second-line or subsequent therapy option for DLBCL in patients who are not candidates for transplant.†*

*It is unclear if tafasitamab will have a negative impact on the efficacy of subsequent anti-CD19 CAR T-cell therapy.

†NCCN makes no warranties of any kind whatsoever regarding their content, use, or application and disclaims any responsibility for their application or use in any way.

IMPORTANT SAFETY INFORMATION

Contraindications: None

Warnings and Precautions:

- **Infusion-Related Reactions (IRRs).** MONJUVI can cause IRRs, including chills, flushing, dyspnea, and hypertension. Premedicate patients and monitor frequently during infusion. Based on the severity of the IRR, interrupt or discontinue MONJUVI and institute appropriate medical management.

Please see the full Prescribing Information for additional Important Safety Information.

DOSAGE AND ADMINISTRATION OF MONJUVI + LENALIDOMIDE[2]

Recommended dosage of MONJUVI and lenalidomide

- MONJUVI should be administered by a healthcare professional with immediate access to emergency equipment and appropriate medical support to manage IRRs
- The recommended dose of MONJUVI is 12 mg/kg based on actual body weight administered as an intravenous infusion according to the dosing schedule on the adjacent page
- Refer to the lenalidomide prescribing information for lenalidomide dosage recommendations
- Administer MONJUVI in combination with lenalidomide 25 mg orally on days 1 to 21 of each 28-day cycle for a maximum of 12 cycles, then continue MONJUVI as monotherapy until disease progression or unacceptable toxicity

RECOMMENDED PREMEDICATIONS[2]

Administer premedications 30 minutes to 2 hours prior to starting MONJUVI infusion to minimize IRRs. Premedications may include acetaminophen, histamine H_1 receptor antagonists, histamine H_2 receptor antagonists, and/or glucocorticosteroids.

For patients not experiencing IRRs during the first 3 infusions, premedication is optional for subsequent infusions.

If a patient experiences an IRR, administer premedications before each subsequent infusion.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions (cont'd):

- **Myelosuppression.** MONJUVI can cause serious or severe myelosuppression, including neutropenia, thrombocytopenia, and anemia. Monitor complete blood counts (CBC) prior to administration of each treatment cycle and throughout treatment. Monitor patients with neutropenia for signs of infection. Consider granulocyte colony-stimulating factor administration. Withhold MONJUVI based on the severity of the adverse reaction. Refer to the lenalidomide prescribing information for dosage modifications.

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DOSAGE AND ADMINISTRATION OF MONJUVI + LENALIDOMIDE (CONT'D)[2]

The cycle length for MONJUVI is 28 days[2]

Cycle 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
MONJUVI 12 mg/kg	■			■				■							■							■						
Lenalidomide 25 mg daily	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●							

Cycles 2 and 3

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
MONJUVI 12 mg/kg	■							■							■							■						
Lenalidomide 25 mg daily	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●							

Cycles 4 to 12

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
MONJUVI 12 mg/kg	■														■													
Lenalidomide 25 mg daily	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●							

After 12 cycles, continue MONJUVI monotherapy 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
MONJUVI 12 mg/kg	■														■													

- 45.7% of patients (37/81) had at least one dose reduction of lenalidomide[3]
- 77.5% of patients (62/81) were able to receive a lenalidomide dose of ≥20 mg/day over the duration of their treatment[3]

For information about the storage and handling of MONJUVI or how MONJUVI is supplied, please refer to the full Prescribing Information.

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DOSAGE MODIFICATIONS FOR ADVERSE REACTIONS[2]

- In the L-MIND study, IRRs occurred in 6% of the 81 patients. 80% of IRRs occurred during cycle 1 or 2[2]

Management guidelines for IRRs and myelosuppression

Infusion-related reactions (IRRs)	
Severity	**Dosage Modification**
GRADE 2 (moderate)	• 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
GRADE 3 (severe)	• 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
GRADE 4 (life-threatening)	• Stop the infusion immediately and permanently discontinue MONJUVI

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DOSAGE MODIFICATIONS FOR ADVERSE REACTIONS (CONT'D)[2]

Myelosuppression	
Severity	**Dosage Modification**
Platelet count of 50,000/mcL or less	• Withhold MONJUVI and lenalidomide and monitor CBC weekly until platelet count is 50,000/mcL or higher • Resume MONJUVI at the same dose and lenalidomide at a reduced dose. Refer to lenalidomide prescribing information for dosage modifications
Neutrophil count of 1,000/mcL or less for at least 7 days **OR** **Neutrophil count of 1,000/mcL or less with an increase of body temperature to 100.4 °F (38 °C) or higher** **OR** **Neutrophil count less than 500/mcL**	• Withhold MONJUVI and lenalidomide and monitor CBC weekly until neutrophil count is 1,000/mcL or higher • Resume MONJUVI at the same dose and lenalidomide at a reduced dose. Refer to the lenalidomide prescribing information for dosage modifications

CBC=complete blood count.

Refer to the lenalidomide prescribing information for lenalidomide dosage recommendations.

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PREPARATION AND ADMINISTRATION FOR MONJUVI

- Reconstitute and dilute MONJUVI prior to infusion[2]

Reconstitution[2]

1. Calculate the dose (mg) and determine the number of vials needed.
2. Reconstitute each 200 mg MONJUVI vial with 5 mL Sterile Water for Injection, USP with the stream directed toward the wall of each vial to obtain a final concentration of 40 mg/mL tafasitamab-cxix.
3. Gently swirl the vial(s) until completely dissolved. Do not shake or swirl vigorously. Complete dissolution may take up to 5 minutes.
4. Visually inspect the reconstituted solution for particulate matter or discoloration. The reconstituted solution should appear as a colorless to slightly yellow solution. Discard the vial(s) if the solution is cloudy, discolored, or contains visible particles.
5. Use the reconstituted MONJUVI solution immediately. If needed, store the reconstituted solution in the vial for a maximum of 12 hours either refrigerated at 36 °F to 46 °F (2 °C to 8 °C) or room temperature at 68 °F to 77 °F (20 °C to 25 °C) before dilution. Protect from light during storage.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions (cont'd):

- **Infections.** Fatal and serious infections, including opportunistic infections, occurred in patients during treatment with MONJUVI and following the last dose. 73% of the 81 patients developed an infection. The most frequent infections were respiratory tract infection, urinary tract infection, bronchitis, nasopharyngitis and pneumonia. Grade 3 or higher infection occurred (30% of 81 patients). The most frequent grade 3 or higher infection was pneumonia. Infection-related deaths were reported (2.5% of 81 patients). Monitor patients for signs and symptoms of infection and manage infections as appropriate.

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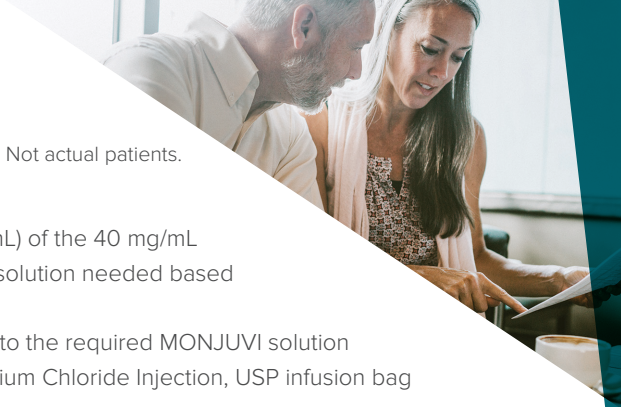

Not actual patients.

Dilution[2]

1. Determine the volume (mL) of the 40 mg/mL reconstituted MONJUVI solution needed based on the required dose.
2. Remove a volume equal to the required MONJUVI solution from a 250 mL 0.9% Sodium Chloride Injection, USP infusion bag and discard it.
3. Withdraw the necessary amount of MONJUVI and slowly dilute in the infusion bag that contains the 0.9% Sodium Chloride Injection, USP to a final concentration of 2 mg/mL to 8 mg/mL. Discard any unused portion of MONJUVI remaining in the vial.
4. Gently mix the intravenous bag by slowly inverting the bag. *Do not shake.* Visually inspect the infusion bag with the diluted MONJUVI infusion solution for particulate matter and discoloration prior to administration.
5. If not used immediately, store the diluted MONJUVI infusion solution refrigerated for up to 18 hours at 36 °F to 46 °F (2 °C to 8 °C) and/or at room temperature for up to 12 hours at 68 °F to 77 °F (20 °C to 25 °C). The room temperature storage includes time for infusion. Protect from light during storage.

Do not shake or freeze the reconstituted or diluted infusion solutions.

Administration[2,4]

1. Administer MONJUVI as an intravenous infusion.[2]
   - For the first infusion, use an infusion rate of 70 mL/h for the first 30 minutes, then, increase the rate so that the infusion is administered within 1.5 to 2.5 hours[2]
     - —In the L-MIND study, after the first 30 minutes, the rate of infusion was increased to 125 mL/h over a 2-hour period[4]
   - Administer all subsequent infusions within 1.5 to 2 hours[2]
   - In the L-MIND study, vital signs were measured immediately prior to infusion, at 15 minutes (+/- 5 minutes), 30 minutes (+/- 10 minutes), every 60 minutes (+/- 15 minutes), and at the end of the infusion (+/- 20 minutes)[4]
2. Infuse the entire contents of the bag containing MONJUVI.[2]
3. Do not co-administer other drugs through the same infusion line.[2]
4. No incompatibilities have been observed between MONJUVI with infusion containers made of polypropylene (PP), polyvinylchloride (PVC), polyethylene (PE), polyethylenterephthalate (PET), or glass and infusion sets made of polyurethane (PUR) or PVC.[2]

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COUNSELING YOUR PATIENTS[2]

Advise the patient to read the FDA-approved patient labeling (Patient Information). Advise your patients to contact their healthcare provider if they experience signs and symptoms of:

➤ Infusion-related reactions

- Advise patients to contact their healthcare provider if they experience signs and symptoms of infusion-related reactions

➤ Myelosuppression

- Fever of 100.4 °F (38 °C) or greater, or bruising or bleeding should be reported immediately
- Advise patients of the need for periodic monitoring of blood counts

➤ Infections

- Fever of 100.4 °F (38 °C) or greater or signs or symptoms of infection should be reported immediately

➤ Embryo-fetal toxicity

- Advise pregnant women of the potential risk to a fetus. Women of reproductive potential should inform their healthcare provider of a known or suspected pregnancy
- Advise women of reproductive potential to use effective contraception during treatment with MONJUVI and for at least 3 months after the last dose
- Advise patients that lenalidomide has the potential to cause fetal harm and has specific requirements regarding contraception, pregnancy testing, blood and sperm donation, and transmission in sperm. Lenalidomide is only available through a REMS program

➤ Lactation

- Advise women not to breastfeed during treatment with MONJUVI and for at least 3 months after the last dose

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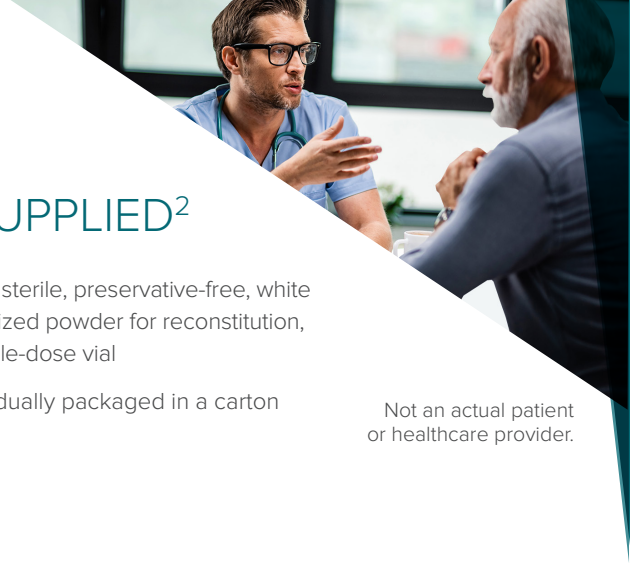

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HOW MONJUVI IS SUPPLIED[2]

- MONJUVI for injection is a sterile, preservative-free, white to slightly yellowish lyophilized powder for reconstitution, supplied as a 200-mg single-dose vial
- Each 200-mg vial is individually packaged in a carton (NDC 73535-208-01)

STORAGE AND HANDLING OF MONJUVI[2]

- Store refrigerated at 36 °F to 46 °F (2 °C to 8 °C) in the original carton to protect from light
- Do not shake
- Do not freeze

IMPORTANT SAFETY INFORMATION

Warnings and Precautions (cont'd):

- **Embryo-Fetal Toxicity.** Based on its mechanism of action, MONJUVI may cause fetal B-cell depletion when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus and women of reproductive potential to use effective contraception during treatment with MONJUVI and for at least 3 months after the last dose. The combination of MONJUVI with lenalidomide is contraindicated in pregnant women. Refer to the lenalidomide prescribing information on use during pregnancy.

Adverse Reactions: The most common adverse reactions (≥20%) were neutropenia (51%), fatigue (38%), anemia (36%), diarrhea (36%), thrombocytopenia (31%), cough (26%), pyrexia (24%), peripheral edema (24%), respiratory tract infection (24%), and decreased appetite (22%).

You may report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch. You may also report side effects to MORPHOSYS US INC. at (844) 667-1992.

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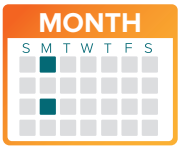
To create a customized infusion schedule for your patients, visit **MonjuviHCP.com**



To find information and resources for your patients, visit **MONJUVI.com**

My MISSION SUPPORT Patient Support Program™

My MISSION Support can help you understand health insurance coverage requirements, answer billing and coding questions, and enroll eligible patients in all program services, including financial assistance programs, helping to secure appropriate access to MONJUVI for eligible patients. My MISSION Support's Program Specialists offer personalized assistance, with the goal of making MONJUVI access simple and streamlined, while providing holistic, compassionate support.

Call **(855) 421-6172**, Monday to Friday, 8 AM to 8 PM ET, for personalized support from a My MISSION Support Program Specialist, or visit **MyMISSIONSupport.com** to learn more.

REFERENCES: 1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for B-Cell Lymphomas V.4.2020. © National Comprehensive Cancer Network, Inc. 2020. All rights reserved. Accessed August 24, 2020. To view the most recent and complete version of the guideline, go online to NCCN.org. **2.** MONJUVI Prescribing Information. Boston, MA: MorphoSys. **3.** Data on file. CSR. MorphoSys. Boston, MA. **4.** Salles G, Duell J, Gonzáles Barca E, et al. Tafasitamab plus lenalidomide in relapsed or refractory diffuse large B-cell lymphoma (L-MIND): a multicentre, prospective, single-arm, phase 2 study. *Lancet Oncol.* 2020;21(7):978-988. doi:/10.1016/S1470-2045(20)30225-4.

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