



# PRODUCT INFORMATION

## INDICATIONS AND 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).

## IMPORTANT SAFETY INFORMATION

**Contraindications:** None

### Warnings and Precautions:

- **Infusion-Related Reactions (IRRs).** MONJUVI can cause IRRs, including fever, chills, rash, 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.
- **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.

*(continued on page 6)*

Please see additional Important Safety Information on page 6 and the Full [Prescribing Information](#).

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<b>Manufactured by</b>	Incyte Corporation 855-463-3463
<b>Marketed by</b>	Incyte Corporation <a href="http://www.Incyte.com">www.Incyte.com</a>
<b>Product Name</b>	MONJUVI
<b>Established Name</b>	tafasitamab-cxix
<b>Product Website</b>	<a href="http://www.MONJUVIHCP.com">www.MONJUVIHCP.com</a>



Not actual size

**NCCN**  
PREFERRED

### National Comprehensive Cancer Network<sup>®</sup> (NCCN<sup>®</sup>) Preferred Treatment Option

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines<sup>®</sup>) recommend tafasitamab-cxix (MONJUVI) in combination with lenalidomide as a preferred second-line or subsequent therapy option (if not previously used) for DLBCL in patients who are not candidates for transplant (NCCN Category 2A)\*

\*It is unclear if tafasitamab or loncastuximab tesirine or if any other CD19-directed therapy would 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.

PRODUCT INFORMATION	
<b>Description</b>	200 mg single-dose vial as lyophilized powder for reconstitution
<b>Sales Unit</b>	One single-dose vial
<b>Units Per Case</b>	One vial per carton
<b>NDC</b>	10-Digit - 50881-013-03   11-Digit - 50881-0013-03
<b>Global Trade Identification Numbers</b>	00373535208013   30373535208014 (case)

HCPs CODING	PRICING
J9349 (Injection, tafasitamab-cxix, 2mg) Effective April 1, 2021	Wholesale Acquisition Cost (WAC) \$1,395.87 / Vial Established April 2025

Please see Important Safety Information on pages 1 and 6 and the Full [Prescribing Information](#).

## PRODUCT AVAILABILITY

- ▶ MONJUVI is available through a network of Specialty Distributors authorized to distribute and/or dispense the medication. Prescribers who do not wish to use buy-and-bill should check with their preferred Specialty Pharmacy for availability
- ▶ Specialty Pharmacies may obtain access to MONJUVI through the Specialty Distributors listed below

## DISTRIBUTION

- ▶ All orders must be placed with one of the Specialty Distributors listed below:

### **AmerisourceBergen Specialty Distribution**

*Cencora*  
 5025 Plano Parkway, Carrollton, TX 75010  
 Phone: 800-746-6273 | Fax: 800-547-9413  
 Service@asdhealthcare.com  
 www.asdhealthcare.com  
 MONJUVI Item # 58057

### **McKesson Plasma & Biologics**

6535 N State Highway 161, Irving, TX 75039  
 Phone: 877-625-2566 | Fax: 888-752-7276  
 MPBOrders@mckesson.com  
 connect.mckesson.com  
 MONJUVI Item # 1559434

### **Cardinal Health Specialty Pharmaceutical Distribution**

233 Mason Road, LaVergne, TN 37086  
 Phone: 855-855-0708 | Phone: 877-453-3972  
 Fax: 877-274-9897  
 GMB-SPD-Specialty@cardinalhealth.com  
 GMB-SPDOncologySalesTeam@cardinalhealth.com  
 MONJUVI Item # 5653530

### **Oncology Supply**

*Cencora*  
 2801 Horace Shepard Drive, Dothan, AL 36303  
 Phone: 800-633-7555  
 Service@oncologysupply.com  
 www.oncologysupply.com  
 MONJUVI Item # 58057

### **McKesson Specialty Care Distribution**

6535 N State Highway 161, Irving, TX 75039  
 Phone: 800-482-6700  
 mscs.mckesson.com  
 MONJUVI Item # 5010390

## DISPENSING PACK DIMENSIONS (APPROXIMATE)

Depth: 33.5 mm

Height: 76 mm

Width: 37.5 mm

## STORAGE INFORMATION

- ▶ 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
- ▶ 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
- ▶ 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. Do not freeze or shake
- ▶ 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 freeze or shake

## PRODUCT EXPIRATION

- ▶ Expiration date printed on both single-dose vial and carton

## DOSAGE AND ADMINISTRATION HIGHLIGHTS

- ▶ The recommended dose of MONJUVI is 12 mg/kg based on actual body weight administered as an intravenous infusion according to the dosing schedule shown below
- ▶ 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. Refer to the lenalidomide prescribing information for lenalidomide dosage recommendations
- ▶ MONJUVI Dosing Schedule:
  - ▶ Cycle 1 – Days 1, 4, 8, 15 and 22
  - ▶ Cycles 2 and 3 – Days 1, 8, 15 and 22
  - ▶ Cycle 4 and beyond – Days 1 and 15
- ▶ MONJUVI should be administered by a healthcare professional with immediate access to emergency equipment and appropriate medical support to manage infusion-related reactions (IRRs)

See Full [Prescribing Information](#) for additional details on dosing and administration including preparing the infusion, prophylaxis for infusion related reactions, and dose modifications for adverse reactions.

## RECONSTITUTION

- ▶ Calculate the dose (mg) and determine the number of vials needed
- ▶ 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
- ▶ Gently swirl the vial(s) until completely dissolved. Do not shake or swirl vigorously. Complete dissolution may take up to 5 minutes
- ▶ 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
- ▶ 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

## DILUTION

- ▶ Determine the volume (mL) of the 40 mg/mL reconstituted MONJUVI solution needed based on the required dose
- ▶ Remove a volume equal to the required MONJUVI solution from a 250 mL 0.9% Sodium Chloride Injection, USP infusion bag and discard it
- ▶ 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
- ▶ 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
- ▶ 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

Please see Important Safety Information on pages 1 and 6 and the Full [Prescribing Information](#).

## PRODUCT ORDER AND RETURN INFORMATION

- ▶ For information on ordering, please call:  
Phone: 833-958-2078
- ▶ Credit for returns is subject to Incyte's current Return Goods Policy  
For more information, please call:  
Phone: 866-765-0919
- ▶ For returns of expired product or product damaged in shipment, please contact your distributor

## ADVERSE EVENT REPORTING

- ▶ Contact Incyte Corporation or the FDA to report an adverse event:

**Incyte Corporation**

Phone: 855-463-3463

Email: [medinfo@incyte.com](mailto:medinfo@incyte.com)

**FDA**

Phone: 1-800-FDA-1088

Web: [www.fda.gov/medwatch](http://www.fda.gov/medwatch)

## PRODUCT COMPLAINTS

- ▶ For product complaints other than adverse event reporting, please contact Incyte Corporation at:  
Phone: 855-463-3463      Email: [medinfo@incyte.com](mailto:medinfo@incyte.com)

## US MEDICAL INFORMATION INQUIRIES

- ▶ For all medical information questions, please contact Incyte Corporation at:  
Phone: 855-463-3463      Email: [medinfo@incyte.com](mailto:medinfo@incyte.com)

## INCYTECARES FOR MONJUVI

### We're Here to Support Your Eligible Patients During Treatment

- ▶ Our mission is to help your patients start and stay on therapy by assisting with access and as-needed support

### Information and resources available through IncyteCARES for MONJUVI include:

- ▶ Benefits verification and prior authorization or appeal support
- ▶ Information about savings and financial assistance options\*
- ▶ Practice resources and forms

### For more information and resources for Healthcare Professionals:

- ▶ Visit [HCP.IncyteCARES.com/MONJUVI](http://HCP.IncyteCARES.com/MONJUVI)
- ▶ Call IncyteCARES for MONJUVI at **1-855-452-5234**, Monday through Friday, 8 AM–8 PM ET

\* Terms and conditions apply. Program terms may change at any time.

## IMPORTANT SAFETY INFORMATION *(continued)*

### Warnings and Precautions *(continued)*:

- **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.
- **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 ( $\geq 20\%$ ) 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%).

Please see the Full [Prescribing Information](#).

**REFERENCES: 1.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for B-Cell Lymphomas V.2.2024. © National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed April 30, 2024. To view the most recent and complete version of the guideline, go online to NCCN.org.



**MONJUVI**<sup>®</sup>  
tafasitamab-cxix | 200mg  
for injection, for intravenous use



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