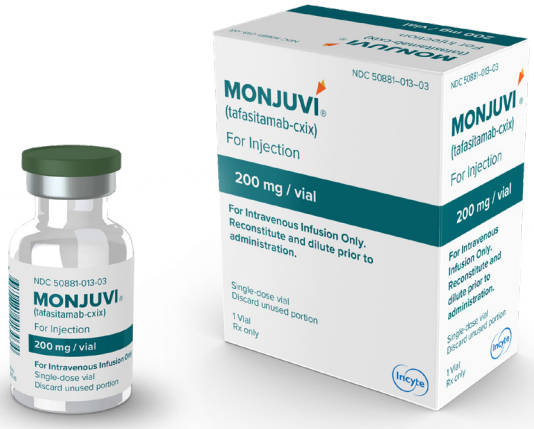
Product Information & Distribution Guide

MONJUVI
tafasitamab-cxix
rituximab & lenalidomide

Manufactured By	Incyte Corporation - **1-855-463-3463**
Marketed By	Incyte Corporation - **www.Incyte.com**
Product Name	MONJUVI
Generic Name	tafasitamab-cxix
Product Website	**www.MONJUVIHCP.com/FL**



National Drug Code (NDC)

10-Digit:	11-Digit:
50881-013-03	50881-**0**013-03

HCPCS Coding

J9349 (Injection, tafasitamab-cxix, 2 mg)
Effective April 1, 2021

Wholesale Acquisition Cost (WAC)

$1,395.87 / Vial
WAC current as of April 2025

Product Bar Codes

Use the barcodes shown here to facilitate the loading of MONJUVI into your EHR platform.

Carton

Vial

EHR, electronic health record; HCPCS, Healthcare Common Procedure Coding System.

FOR FL

INDICATIONS & USAGE

Follicular Lymphoma

MONJUVI (tafasitamab-cxix), in combination with lenalidomide and rituximab, is indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL).

Limitations of Use: MONJUVI is not indicated and is not recommended for the treatment of patients with relapsed or refractory marginal zone lymphoma outside of controlled clinical trials.

IMPORTANT SAFETY INFORMATION

Contraindications:

None.

Warnings and Precautions:

- **Infusion-Related Reactions (IRRs).** MONJUVI (tafasitamab-cxix) 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.

Please see additional Important Safety Information throughout and the full Prescribing Information for more information about MONJUVI.

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

Ordering & Distribution

MONJUVI is available through the following network of specialty distributors:

CardinalHealth™ | cencora | McKESSON

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 above.

How Supplied

Sales Unit	One single-dose vial: 200 mg		
Units Per Carton	One vial per carton		
Pack Dimensions (Approximate)	**Depth**	**Height**	**Width**
	33.5 mm	76 mm	37.5 mm
Global Trade Identification Numbers	00373535208013 30373535208014 (case)		
Product Expiration	Expiration date printed on both single-dose vial and carton		

Description

Sterile, preservative-free, white to slightly yellowish lyophilized powder for reconstitution supplied as a 200 mg single-dose vial.

Storage & Handling

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)

- **Myelosuppression.** MONJUVI can cause serious or severe myelosuppression, including neutropenia, lymphopenia, thrombocytopenia, and anemia. Monitor complete blood counts (CBCs) before 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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Contact Information

Product Information

For additional information on MONJUVI, please contact:

Phone: 1-855-463-3463
Email: MedInfo@Incyte.com

Product Returns

Credit for returns is subject to Incyte's current Specialty Return Goods Policy. Please request a Return Goods Authorization by calling:

1-855-751-7958

US Medical Information Inquiries

For all medical information requests, please contact Incyte Medical Information:

Phone: 1-855-463-3463
Email: MedInfo@Incyte.com

Adverse Event Reporting

Contact Incyte or the FDA to report an adverse event.

Incyte:
Phone: 1-855-463-3463
Email: MedInfo@Incyte.com

FDA:
Phone: 1-800-FDA-1088
Web: www.fda.gov/medwatch

Dosage & Administration Highlights

Important Dosing Information

MONJUVI should be administered by a healthcare professional with immediate access to emergency equipment and appropriate medical support to manage infusion-related reactions.

Recommended Dosage of MONJUVI for Follicular Lymphoma (FL)

The recommended dose of MONJUVI is 12 mg/kg based on actual body weight administered as an intravenous infusion in combination with lenalidomide and rituximab, according to the dosing schedule below.

Cycle[a]	Dosing Schedule
Cycles 1 to 3	Days 1, 8, 15, and 22
Cycles 4 to 12	Days 1 and 15

[a] Each treatment cycle is 28 days.

Administer MONJUVI in combination with rituximab 375 mg/m^2 (Cycles 1 to 5) and lenalidomide 20 mg (Days 1-21 in Cycles 1 to 12). Refer to the rituximab prescribing information and the lenalidomide prescribing information for the respective dosage recommendations, including lenalidomide dosage recommendations for patients with renal insufficiency.

See full Prescribing Information for additional details on dosing and administration including recommended premedications and dose modifications for adverse reactions.

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. Among 274 patients with FL who received MONJUVI in combination with lenalidomide and rituximab in inMIND, Grade 3 or higher infections occurred in 24%. Monitor patients for signs and symptoms of infection and manage infections as appropriate. Consider infection prophylaxis per institutional guidelines. Consider treatment with subcutaneous or intravenous immunoglobulin (IVIG) as appropriate.

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Dosage & Administration Highlights (CONT'D)

Preparation and Administration

Reconstitute and dilute MONJUVI prior to infusion.

Reconstitution

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.

Dilution

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

- Administer MONJUVI as an intravenous infusion.
  - 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.
  - Administer all subsequent infusions within 1.5 to 2 hours.
- Infuse the entire contents of the bag containing MONJUVI.
- Do not co-administer other drugs through the same infusion line.
- No incompatibilities have been observed between MONJUVI with infusion containers made of polypropylene (PP), polyvinylchloride (PVC), polyethylene (PE), polyethylene terephthalate (PET), or glass and infusion sets made of polyurethane (PUR) or PVC.

Patient Support Program

IncyteCARES for MONJUVI Supports Eligible Patients During Treatment

The IncyteCARES mission is to help patients start and stay on therapy by assisting with access and as-needed support.

IncyteCARES can help patients understand their health insurance coverage, can provide reimbursement support, and offers savings, financial assistance, and support options for eligible patients,* including:

IncyteCARES for MONJUVI Savings Program
For eligible patients with commercial health insurance

IncyteCARES for MONJUVI Patient Assistance Program
For eligible patients who are uninsured or underinsured for MONJUVI

Information About Nonprofit or Other Support Organizations
For all patients

IncyteCARES

The IncyteCARES Team Is Available by Phone Every Weekday
Call **1-855-452-5234**, Monday to Friday, 8 AM - 8 PM ET
Visit **HCP.IncyteCARES.com/MONJUVI** to learn more

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

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 3 months after the last dose. The combination of MONJUVI with lenalidomide and rituximab is contraindicated in pregnant women. Refer to the lenalidomide prescribing information on use during pregnancy.

Adverse Reactions:

The most common adverse reactions (≥ 20%) in patients with FL receiving MONJUVI were respiratory tract infections (56%) (including COVID-19 infection and pneumonia), diarrhea (38%), rash (37%), fatigue (34%), constipation (29%), musculoskeletal pain (24%), and cough (21%). The most common Grade 3 or 4 laboratory abnormalities (≥ 20%) were decreased neutrophils (48%) and decreased lymphocytes (22%).

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