EMBLAVEO™
aztreonam and avibactam
for injection (2 g)

DOSING & ADMINISTRATION

The first and only combination of aztreonam and avibactam in a single therapy[1]

Product shown is not actual size.

With in vitro activity against all 4 classes of β-lactamase and dosing optimized based on robust PK/PD analyses[1-3]*

In vitro activity does not necessarily correlate with clinical efficacy results.

PD, pharmacodynamic; PK, pharmacokinetic.

*In vitro activity demonstrated against class A (*Klebsiella pneumoniae* carbapenemase, extended-spectrum β-lactamase), class B (New Delhi metallo-β-lactamase, imipenemase, Verona integron-encoded metallo-β-lactamase), class C (AmpC), and class D (oxacillinase-48–like) carbapenem-resistant Enterobacterales (CRE).[1,2]

INDICATIONS AND USAGE

Complicated Intra-abdominal Infections

EMBLAVEO, in combination with metronidazole, is indicated in patients 18 years and older who have limited or no alternative treatment options for the treatment of complicated intra-abdominal infections (cIAI) including those caused by the following susceptible gram-negative microorganisms: *Escherichia coli*, *Klebsiella pneumoniae*, *Klebsiella oxytoca*, *Enterobacter cloacae complex*, *Citrobacter freundii complex*, and *Serratia marcescens*. Approval of this indication is based on limited clinical safety and efficacy data for EMBLAVEO.

Usage to Reduce Development of Drug-Resistant Bacteria

To reduce the development of drug-resistant bacteria and maintain the effectiveness of EMBLAVEO and other antibacterial drugs, EMBLAVEO should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

EMBLAVEO is contraindicated in patients with known hypersensitivity to the components of EMBLAVEO (aztreonam and avibactam).

Please see full Important Safety Information throughout. Please also see accompanying full Prescribing Information or visit https://www.rxabbvie.com/pdf/emblaveo_pi.pdf.

Recommended dosing[1]

After an initial loading dose, EMBLAVEO™ is dosed every 6 hours for 5 to 14 days[1]

- Metronidazole should be given concurrently
- The required loading dose improves the joint probability of target attainment (PTA) in the first 6-hour dosing interval[3]

INFUSION TIME: 3 HOURS
INTERVAL: EVERY 6 HOURS

DAILY TOTALS (DAY 2 ONWARD):
AZTREONAM: 6 g
AVIBACTAM: 2 g

EMBLAVEO dosing is supported by PK/PD modeling and simulations[3]

*For patients with CLcr ≤50 mL/min, see full Prescribing Information for dose adjustments.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Hypersensitivity reactions were noted in patients treated with EMBLAVEO, including rash, flushing, and bronchospasm. Prior to treatment, it should be established if the patient has a history of hypersensitivity reactions to components of EMBLAVEO (aztreonam and avibactam). In case of hypersensitivity reactions, immediately discontinue EMBLAVEO and initiate appropriate medications and/or supportive care.

EMBLAVEO dosing should be adjusted based on the patient's estimated creatinine clearance[1]

Estimated CLcr (mL/min)†	Loading dose‡	Maintenance dose‡	Infusion time	Dosing interval§
>50	2.67 g	2 g	3 HOURS	EVERY 6 HOURS
>30 to ≤50	2.67 g	1 g	3 HOURS	EVERY 6 HOURS
>15 to ≤30	1.8 g	0.9 g	3 HOURS	EVERY 8 HOURS
≤15, including on hemodialysis¶	1.33 g	0.9 g	3 HOURS	EVERY 12 HOURS

†Calculated using the Cockcroft-Gault formula.

‡Aztreonam-avibactam is a combination product in a fixed 3:1 ratio.

§Dosing interval is calculated from the start of one infusion to the start of the subsequent infusion.

¶Both aztreonam and avibactam are removed by hemodialysis; EMBLAVEO should be administered after the hemodialysis session on hemodialysis days.

A single loading dose is followed by maintenance doses beginning at the next dosing interval.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS

Serious Skin Disorders

Cases of toxic epidermal necrolysis have been reported in association with aztreonam (a component of EMBLAVEO) in patients undergoing bone marrow transplant with multiple risk factors including sepsis, radiation therapy, and other concomitantly administered drugs associated with toxic epidermal necrolysis. Discontinue EMBLAVEO if a serious skin reaction occurs.

Hepatic Adverse Reactions

Elevations in hepatic transaminases have been observed during treatment with EMBLAVEO. Monitoring of liver-related laboratory tests is recommended while on treatment, particularly in patients with baseline liver comorbidities or on concomitant hepatotoxic medications. If transaminase elevations are noted, consider discontinuing EMBLAVEO, if clinically indicated, and monitor the patient for resolution of any pertinent clinical and laboratory findings.

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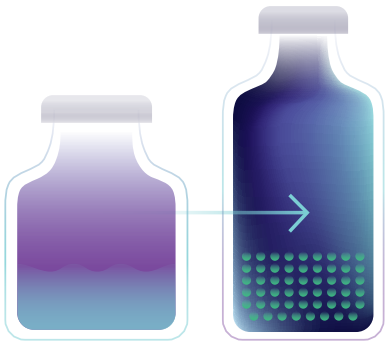
Preparation and storage[1]

Prior to reconstitution: Store refrigerated at 2°C to 8°C (36°F to 46°F).
Protect from light. Store in carton until time of use. Please see Prescribing Information for full preparation guidelines.



1 **Reconstitute the powder** in the EMBLAVEO™ vial with 10 mL of sterile water for injection.

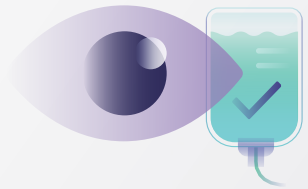
2 **Mix gently, and then withdraw the required volume for the indicated dose**
Refer to the Prescribing Information to calculate the volume of reconstituted EMBLAVEO solution required to prepare the recommended dose.

3 **Before infusion, dilute the withdrawn volume** of the reconstituted EMBLAVEO solution further to a final volume of 50 to 250 mL in an infusion bag containing either 0.9% sodium chloride injection, 5% dextrose injection, or lactated Ringer's injection.

Aztreonam concentration:
2.7 to 40 mg/mL

Avibactam concentration:
0.9 to 13.3 mg/mL

4 **Visually inspect the diluted EMBLAVEO solution**
Ensure contents are dissolved completely. The color of the EMBLAVEO infusion solution for administration ranges from clear to light yellow.



60 MIN

Storage

Upon reconstitution with sterile water for injection, the reconstituted EMBLAVEO solution may be held for up to 60 minutes at 30°C (86°F) under ambient light prior to transfer and dilution in a suitable infusion bag.

Following dilution with 0.9% sodium chloride or lactated Ringer's injection:
EMBLAVEO solutions in the infusion bags may be refrigerated at 2°C to 8°C (36°F to 46°F) for up to 24 hours, followed by 12 hours at not more than 30°C (86°F) under ambient light.

Following dilution with 5% dextrose injection:
EMBLAVEO solutions in the infusion bags may be refrigerated at 2°C to 8°C (36°F to 46°F) for up to 24 hours, followed by 4 hours at not more than 30°C (86°F) under ambient light.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS

***Clostridioides Difficile*-Associated Diarrhea**
Clostridioides difficile-associated diarrhea (CDAD) has been reported for nearly all systemic antibacterial drugs, including EMBLAVEO, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial drugs alters the normal flora of the colon and may permit overgrowth of *C. difficile*. *C. difficile* produces toxins A and B which contribute to the development of CDAD. Hypertoxin producing strains of *C. difficile* cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibacterial use. Careful medical history is necessary because CDAD has been reported to occur more than 2 months after the administration of antibacterial drugs. If CDAD is suspected or confirmed, antibacterial drugs not directed against *C. difficile* may need to be discontinued. Manage fluid and electrolyte levels as appropriate, supplement protein intake, monitor antibacterial treatment of *C. difficile*, and institute surgical evaluation as clinically indicated.

Development of Drug-Resistant Bacteria
Prescribing EMBLAVEO in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

IMPORTANT SAFETY INFORMATION (continued)

ADVERSE REACTIONS

The most common adverse reactions occurring at an incidence of greater than 5% were hepatic adverse reactions, anemia, diarrhea, hypokalemia, and pyrexia.

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ONE BAG. ONE LINE.

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EMBLAVEO™ is delivered in 4 divided doses per day via extended 3-hour infusions to optimize drug exposure[1]*

IV BAGS NEEDED OVER A 24-HOUR PERIOD

3-hour infusion time for each maintenance dose

- The only FDA-approved dosing regimen that delivers **2 g of avibactam and 6 g of aztreonam** per day†
- The maintenance dose is 1.5 g of aztreonam and 0.5 g of avibactam†
- Single-line administration

SCAN THIS CODE
or visit EMBLAVEO.com for more information

*For patients with CLcr ≤50 mL/min, see full Prescribing Information for dose adjustments.
†Recommended dosage for adults with estimated CLcr ≥50 mL/min, calculated using the Cockcroft-Gault formula.

INDICATIONS AND USAGE

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CONTRAINDICATIONS

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References: 1. EMBLAVEO. Prescribing Information. AbbVie, Inc. 2025. **2.** Castanheira M, Maher JM, Simpson K, Hubler C, Sader HS. Poster presented at: Infectious Disease Week 2023; October 11-15, 2023; Boston, MA. **3.** Das S, Riccobene T, Carrothers TJ, et al. *Eur J Clin Pharmacol.* 2024;80(4):529-543. doi:10.1007/s00228-023-03609-x

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ACHIEVING OPTIMAL DOSING[1]

PK and PD were extensively studied for EMBLAVEO™

PD, pharmacodynamics; PK, pharmacokinetics.

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DOSING INFORMED BY ROBUST PK/PD STUDIES[1]

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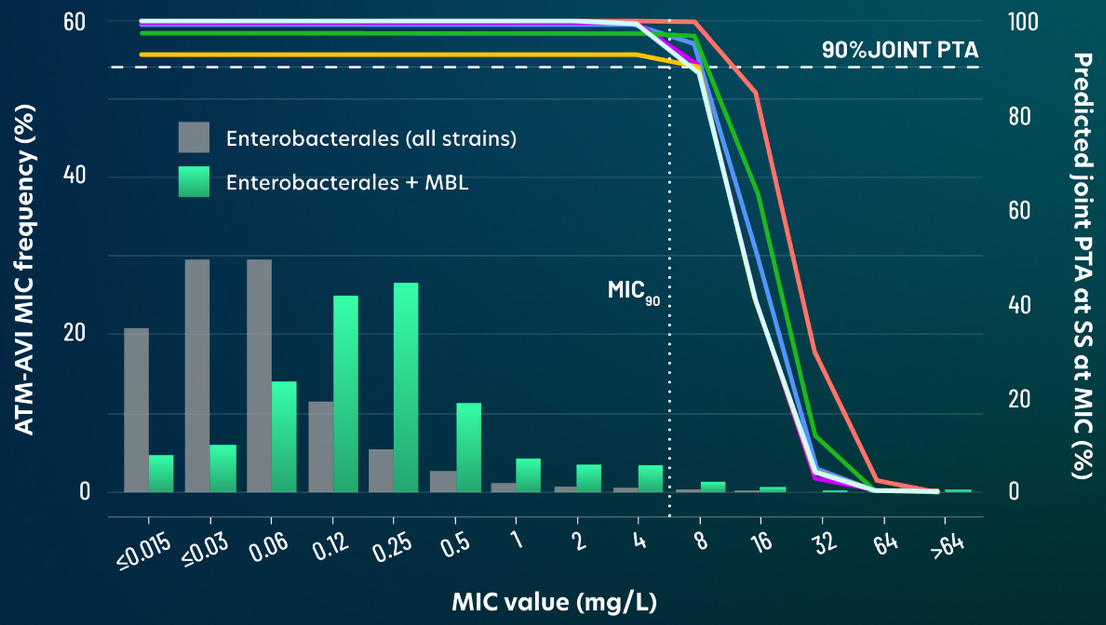
PREDICTED JOINT PTA FOR PATIENTS WITH cIAI ACROSS RENAL FUNCTION GROUPS[1]*

Renal function (CLcr, mL/min)

- Augmented (>150)
- Normal (>80 to 150)
- Mild impairment (>50 to 80)
- Moderate impairment (>30 to 50)
- Severe impairment (>15 to 30)
- End-stage renal disease (≤15)†



2 G OF AVIBACTAM

with 6 g of aztreonam daily, infused over 3 hours, was needed to achieve 90% joint probability of target attainment (PTA)[1]

- >99% of Enterobacterales, including MBL producers, are inhibited in vitro at MIC ≤4 mg/L[2]
- The dose regimen provides coverage across the MIC distribution[1]

AT THE APPROVED DOSES,

EMBLAVEO™ ACHIEVED ~90% JOINT PTA ACROSS RENAL FUNCTION GROUPS[1‡]

ATM-AVI, aztreonam-avibactam; cIAI, complicated intra-abdominal infection; MBL, metallo-β-lactamase; MIC, minimum inhibitory concentration; SS, steady state.

In joint PTA analyses, the primary target for aztreonam was 60% *f*T > MIC of 8 mg/L and the primary target for avibactam (in combination with aztreonam in EMBLAVEO) was 50% *f*T > 2.5 mg/L.

*Based on phase 3 population PK modeling and simulations of 5000 patients who met the ATM-AVI PK/PD targets simultaneously at steady state following receipt of a single loading dose and maintenance doses adjusted as recommended for renal function and overlaid on the ATM-AVI MIC distribution of Enterobacterales, including MBL-producing strains, collected from 2017 to 2021 as part of ATM-AVI susceptibility surveillance studies.

†Both ATM and AVI are removed by hemodialysis; ATM-AVI should be administered after the hemodialysis session on hemodialysis days.

‡With recommended dosing for renal function, calculated using the Cockcroft-Gault formula.

IMPORTANT SAFETY INFORMATION (continued)

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