



EMBLAVEO™
aztreonam and avibactam
for injection (2 g)

SUSCEPTIBILITY TESTING

MANUAL DIAGNOSTICS

DESCRIPTION	FDA CLEARED	AVAILABLE	CATALOG NUMBER	ORDER QUANTITY
HardyDisk™ Aztreonam/Avibactam, (Emblaveo™) 30/20mcg (AZA50)	Yes	Yes	Z9481	50 disks
			Z9485	250 disks
Oxoid™ Disc AST Aztreonam-Avibactam, 30/20mcg	Yes	<Availability>	<Catalog Number>	<Order Quantity>
bioMérieux ETEST® (MIC Test Strip) Aztreonam/Avibactam	Yes	<Availability>	<Catalog Number>	<Order Quantity>
Liofilchem® MTS™ (MIC Test Strip) Aztreonam and Avibactam	Yes	Yes	22-778-083	10 Strips
			22-778-082	30 Strips
			22-778-081	100 Strips

FDA = Food and Drug Administration; MIC = minimum inhibitory concentration.

HardyDisk is a registered trademark of Hardy Diagnostics.

Oxoid™ is owned by Thermo Fisher Scientific.

ESTEST™ is a registered trademark of bioMérieux SA or one of its subsidiaries.

Liofilchem® is a registered trademark of LIOFILCHEM s.r.l.

MTS™ is registered by LIOFILCHEM s.r.l.

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. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

Please see additional Important Safety Information throughout.

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



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SUSCEPTIBILITY TESTING

MIC TESTING AVAILABLE AT REFERENCE LABS

Request isolate testing by phone at [1-440-835-4458](tel:1-440-835-4458) or email info@labspec.org

Susceptibility testing is available through the CDC's [Antimicrobial Resistance Laboratory Networks](#) for isolates that are non-susceptible to all β -lactams or positive for MBL.

FDA-APPROVED BREAKPOINTS

Pathogen	MINIMUM INHIBITORY CONCENTRATIONS (mcg/mL)			DISK DIFFUSION (ZONE DIAMETERS IN mm)		
	S	I	R	S	I	R
Enterobacterales	<Breakpoint>	<Breakpoint>	<Breakpoint>	<Breakpoint>	<Breakpoint>	<Breakpoint>

FDA = Food and Drug Administration; I = Intermediate; MBL = metallo- β -lactamase; MIC = minimum inhibitory concentration; R = Resistant; S = Susceptible.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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

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.

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.

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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.

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.

ADVERSE REACTIONS

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

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