XACDURO®
(sulbactam for injection; durlobactam for injection), co-packaged for intravenous use

XACDURO® is approved for adult patients with hospital-acquired and ventilator-associated bacterial pneumonia (HABP/VABP) caused by susceptible isolates of *Acinetobacter baumannii–calcoaceticus* complex[1,2]

START WITH STEWARDSHIP

CHOOSE PATHOGEN-TARGETED COVERAGE FOR HABP/VABP CAUSED BY SUSCEPTIBLE ISOLATES OF ABC, INCLUDING CRAB, WITH XACDURO[1,3]

ABC, *Acinetobacter baumannii-calcoaceticus* complex; CRAB, carbapenem-resistant *Acinetobacter baumannii*; HABP/VABP, hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia.

INDICATION & USAGE

Indication

XACDURO® (sulbactam for injection; durlobactam for injection), co-packaged for intravenous use is indicated in adults for the treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP) caused by susceptible isolates of *Acinetobacter baumannii-calcoaceticus* complex.

Limitations of Use

XACDURO is not indicated for the treatment of HABP/VABP caused by pathogens other than susceptible isolates of *Acinetobacter baumannii-calcoaceticus* complex.

Usage

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

SELECTED IMPORTANT SAFETY INFORMATION

Contraindications: XACDURO is contraindicated in patients with a history of known severe hypersensitivity to the components of XACDURO or other beta-lactam antibacterial drugs.

Warnings and Precautions:

- Hypersensitivity was observed in patients treated with XACDURO in clinical trials. Serious and occasionally fatal hypersensitivity (anaphylactic) reactions and serious skin reactions have been reported in patients receiving beta-lactam antibacterial drugs. Before initiating therapy with XACDURO, careful inquiry should be made concerning previous hypersensitivity reactions to carbapenems, penicillins, cephalosporins, other beta lactams, and other allergens. If an allergic reaction occurs, discontinue XACDURO.
- *Clostridioides difficile*-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents and may range in severity from mild diarrhea to fatal colitis. Evaluate if diarrhea occurs. If CDAD is suspected or confirmed, the risk/benefit of continuing treatment with XACDURO should be assessed.

Please see additional Important Safety Information throughout. Before administering, please see the Full Prescribing Information for XACDURO.

ACINETOBACTER HAS BECOME RESISTANT TO MOST ANTIBIOTICS USED TO TREAT HABP/VABP INCLUDING CARBAPENEMS AND THIRD-GENERATION CEPHALOSPORINS.[4]

XACDURO is the only treatment with durlobactam and developed to inhibit class A, C, and D β-lactamases in *Acinetobacter*.[1,5]

Sulbactam: Bactericidal activity against *Acinetobacter*.[1]

- β-lactam penicillin derivative[1,6]

Mechanism of action: Inhibits penicillin-binding proteins 1 and 3 → inhibits bacterial cell wall synthesis[1,5,7]

Durlobactam: A,C, and D β-lactamase inhibitor[5]

- Non-β-lactam diazabicyclooctane β-lactamase inhibitor[1,5,6]

Mechanism of action: Protects sulbactam from hydrolysis → restores activity of sulbactam[1,5,6,a]

[a]Based on *in vitro* studies.

Spectrum of β-lactamase inhibitor activity[8-11,a]

β-lactamase inhibitor[b]	Class A	Class C	Class D	Class B (No inhibitors with broad activity)
Clavulanic acid, Sulbactam, Tazobactam	±	–	–	–
Avibactam, Relebactam, Vaborbactam	+	+	±	–
Durlobactam	+	+	+	–

The general approach for the treatment of HABP/VABP caused by ABC, including CRAB infections, is to administer combination antibiotic therapies with at least 2 agents. It is also suggested that at least 1 agent in the combination is sulbactam-based. **The IDSA guidance recommends XACDURO as the only preferred agent for the treatment of infections caused by CRAB.** The guidance also recommends XACDURO be administered in combination with imipenem-cilastatin or meropenem.[11]

[a]Clinical significance cannot be inferred from *in vitro* data
[b]Approved indications may not include carbapenem-resistant *Acinetobacter baumannii*.
+, active against β-lactamases; –, not active against β-lactamases; ±, active against select β-lactamases.
ABC, *Acinetobacter baumannii-calcoaceticus* complex; CRAB, carbapenem-resistant *Acinetobacter baumannii*; HABP/VABP, hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia; IDSA, Infectious Diseases Society of America.

SELECTED IMPORTANT SAFETY INFORMATION

Warnings and Precautions (cont'd):

- Prescribing XACDURO in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

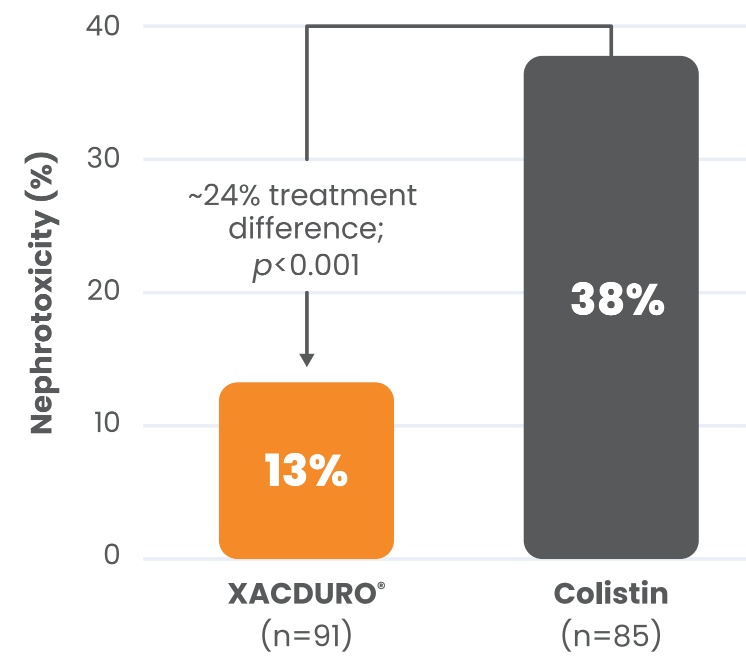
Adverse Reactions: The most common adverse reactions reported in >10% of patients treated with XACDURO were liver test abnormalities (19%), diarrhea (17%), anemia (13%), and hypokalemia (12%).

XACDURO DISPLAYED POWERFUL RESULTS AGAINST HABP/VABP INFECTIONS CAUSED BY ABC.[3]

In the Phase 3 ATTACK non-inferiority trial evaluating the safety and efficacy of XACDURO vs. colistin for patients with serious infections due to ABC, including CRABC strains, XACDURO[1,3]:

- Demonstrated greater clinical cure rates vs. colistin[3]
- Met the primary efficacy endpoint of 28-day all-cause mortality in patients with laboratory-confirmed CRABC (microbiologically modified ITT population)[3]
  - XACDURO (n=63) met non-inferiority criteria versus colistin (n=62) for 28-day all-cause mortality (19% vs. 32.3%; 95% CI, -30 to 3.5)[3]

XACDURO also achieved the primary safety endpoint in ATTACK: Significantly lower incidence of nephrotoxicity versus colistin based on modified RIFLE criteria* at any post-baseline visit[3]



*RIFLE measured by creatinine level or glomerular filtration rate, but not urinary output. Nephrotoxicity defined as meeting any of the RIFLE criteria at any post-baseline visit; if patients had multiple RIFLE events, the patient was counted only once at the highest severity. No patients in this study experienced end-stage renal disease. Nephrotoxicity analysis excluded 1 patient in the colistin group with chronic hemodialysis at baseline.[3]

For patients with creatinine clearance <45 mL/min or ≥130 mL/min, please see Full Prescribing Information.

ABC, *Acinetobacter baumannii-calcoaceticus* complex; ATTACK, *Acinetobacter* Treatment Trial Against Colistin; CRABC, carbapenem-resistant *Acinetobacter baumannii-calcoaceticus* complex; HABP/VABP, hospital-acquired/ventilator-associated bacterial pneumonia; ITT, intent-to-treat; RIFLE, risk, injury, failure, loss, or end-stage renal disease.

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HABP/VABP KILLS QUICKLY
ACT FAST WITH XACDURO

CRAB

Effective against *Acinetobacter baumannii-calcoaceticus* complex including drug-resistant strains such as CRAB[6]

XACDURO was non-inferior to colistin with regard to 28-day all-cause mortality and achieved greater clinical cure rates vs. colistin[3]

Favorable safety profile, with lower incidence of nephrotoxicity than colistin[1,3]

Click here to learn more about pathogen-targeted coverage for HABP/VABP caused by susceptible isolates of ABC, including CRAB with XACDURO

ABC, *Acinetobacter baumannii-calcoaceticus* complex; CRAB, carbapenem-resistant *Acinetobacter baumannii-calcoaceticus;* HABP/VABP, hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia.

SELECTED IMPORTANT SAFETY INFORMATION

Warnings and Precautions (cont'd):

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You are encouraged to report negative side effects of prescription drugs to the FDA. To report SUSPECTED ADVERSE REACTIONS, please contact:

Innoviva Specialty Therapeutics, Inc.™
1-800-651-3861
medinfo@istx.com

U.S. Food and Drug Administration
1-800-FDA-1088
www.fda.gov/medwatch

Please see additional Important Safety Information throughout. Before administering, please see the Full Prescribing Information for XACDURO.

REFERENCES: 1. XACDURO®. Package Insert. Innoviva Specialty Therapeutics, Inc.; 2023. **2.** Data on File. Innoviva Specialty Therapeutics; 2023. **3.** Kaye KS, et al. *Lancet Infect Dis.* 2023;11:s1473–3099(23)00184–6. doi:10.1016/s1473-3099(23)00184–6 **4.** World Health Organization. WHO publishes list of bacteria for which new antibiotics are urgently needed. Accessed February 13, 2026. https://www.who.int/news/item/27-02-2017-who-publishes-list-of-bacteria-for-which-new-antibiotics-are-urgently-needed. Published February 27, 2017 **5.** Papp-Wallace KM, et al. *Clin Infect Dis.* 2023;76(Suppl 2):S194–S201. doi:10.1093/cid/ciad095 **6.** Karlowsky JA, et al. *Antimicrob Agents Chemother.* 2022;66(9):e007812. doi:10.1128/aac.00781-22 **7.** Penwell WF, et al. *Antimicrob Agents Chemother.* 2015;59(3):1680–1689. doi:10.1128/AAC.04808-14 **8.** Eiamphungporn W, et al. *Int J Mol Sci.* 2018;19(8):2222. doi:10.3390/ijms19082222 **9.** Durand-Réville, et al. *Nat Microbiol.* 2017;2:17104. **10.** Sawa T, et al. *J Intensive Care.* 2020 Jan 28;8:13 **11.** Vázquez-Ucha JC, et al. *Int J Mol Sci.* 2020;21(23):9308. doi:10.3390/ijms21239308 **12.** Tamma PD, et al. Infectious Diseases Society of America 2024 Guidance on the Treatment of Antimicrobial-Resistant Gram-Negative Infections. *Clin Infect Dis.* Published online August 7, 2024. doi:10.1093/cid/ciae403

INNOVIVA Specialty Therapeutics™

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