



GRAND VUE
RESORT

STOP

Diagnosis + Antimicrobial Stewardship

Low prevalence

- DAK interventions alone
- No net low impact
- Clinical data gaps
- Several gaps from the
- literature
- Potential for net benefit









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Fall 2018 Educational Symposium
November 16, 2018

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Michelle Harris
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Duke University Medical Center

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John Morris
Achaogen

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Lillia Taschuk
Diversey

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Christopher Hostler
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Duke University Medical Center

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Alicia Nelson
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Chloe Tonney
CDC Foundation

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Amy Hnat
Duke University Hospital

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John Pauluzzi
North Carolina, Inc.

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Jennifer Trueheart
North Carolina Specialty Hospital

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Duke Center for
Antimicrobial Stewardship
and Infection Prevention



Duke Center for
Antimicrobial Stewardship
Prevention







John Smith

John Smith
John Smith
John Smith



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Angelina Davis
Assistant Director
Health University Medical Center







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DUKE
DIAGNOSTIC
OUTREACH
NETWORK

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ANTIMICROBIAL
STEWARDSHIP
OUTREACH
NETWORK

Fall 2018 Symposium
The Impact of Diagnostic
Testing on Infection
Prevention and Antimicrobial
Stewardship

Friday, November 16, 2018

 Duke University
School of Medicine

 Center for
Antimicrobial Stewardship
and Infection Prevention



TETRAPHASE
PHARMACEUTICALS



XERAVA™
(eravacycline) for injection



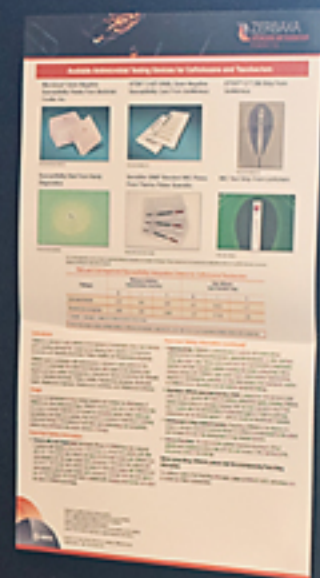
XERAVA™
(eravacycline) for injection

J
JAMA Surgery
Journal of the American College of Surgeons

Reprint Article

Original Investigation

Assessing the Efficacy and Safety of Eravacycline vs
Ertapenem in Complicated Intra-abdominal Infections
in the Investigating Gram-Negative Infections Treated
With Eravacycline (IGNITE 1) Trial
A Randomized Clinical Trial



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When to HLD with trophon2?

Probe will only contact healthy intact skin	Probe may contact mucous membranes and non-intact skin	Probe may contact sterile tissue or blood
Non-Critical <ul style="list-style-type: none">• surface ultrasound probe head	Semi-Critical <ul style="list-style-type: none">• endoscopic scopes• bronchoscopes• surface ultrasound probe head• endoscopes• laparoscopes• colonoscopes• transvaginal probes• transurethral probes• transnasal probes	Critical <ul style="list-style-type: none">• endoscopic procedures• endoscopes• bronchoscopes• laparoscopes• transvaginal probes• transurethral probes• transnasal probes
U/D or HLD	HLD or U/D	HLD or U/D

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MD, PhD
Duke University Medical Center



Scott Smith
Mary Smith

Scott Smith
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Coge

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EXIT

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UVC disinfection
isn't the future,
it's now.



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GRANDOVER







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INDICATIONS & USAGE

ZEMDRI (plazomicin) is indicated in patients 18 years of age or older for the treatment of complicated urinary tract infections (cUTI), including pyelonephritis, caused by the following susceptible microorganisms: *Escherichia coli*, *Klebsiella pneumoniae*, *Proteus mirabilis*, and *Enterobacter cloacae*.

As only limited clinical safety and efficacy data for ZEMDRI are currently available, reserve ZEMDRI for use in cUTI patients who have limited or no alternative treatment options.

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

IMPORTANT SAFETY INFORMATION

BOXED WARNINGS: NEPHROTOXICITY, OTOTOXICITY, NEUROMUSCULAR BLOCKADE AND FETAL HARM

- Nephrotoxicity** has been reported with ZEMDRI. The risk of nephrotoxicity is greater in patients with impaired renal function, the elderly, and in those receiving concomitant nephrotoxic medications. Assess creatinine clearance in all patients prior to initiating therapy and daily during therapy. Therapeutic Drug Monitoring (TDM) is recommended for complicated urinary tract infection (cUTI) patients with CrCl less than 30 mL/min to avoid potentially toxic levels.
- Ototoxicity**, manifested as hearing loss, tinnitus, and/or vertigo, has been reported with ZEMDRI. Symptoms of aminoglycoside-associated ototoxicity may be irreversible and may not become evident until after completion of therapy. Aminoglycoside-associated ototoxicity has been observed primarily in patients with a family history of hearing loss, patients with renal impairment, and in patients receiving higher doses and/or for longer durations of therapy than recommended.
- Aminoglycosides have been associated with neuromuscular blockade with ZEMDRI; monitor for adverse reactions associated with neuromuscular blockade particularly in high-risk patients, such as patients with underlying neuromuscular disorders (including myasthenia gravis) or in patients concomitantly receiving neuromuscular blocking agents.
- Aminoglycosides, including ZEMDRI, can cause fetal harm when administered to a pregnant woman.

Contraindications

ZEMDRI is contraindicated in patients with known hypersensitivity to any aminoglycoside.

Additional Warnings and Precautions

Nephrotoxicity: Reported with the use of ZEMDRI. Most serum creatinine increases were <1 mg/dL, above baseline and reversible. Assess CrCl in all patients prior to initiating therapy and daily during therapy with ZEMDRI, particularly in those at increased risk of nephrotoxicity, such as those with renal impairment, the elderly and those receiving concomitant potentially nephrotoxic medications. In the setting of worsening renal function, the benefit of continuing ZEMDRI should be assessed. Adjust the oral dosage regimen in cUTI patients with CrCl 30 mL/min and 40-60 mL/min. For subsequent doses, TDM is recommended for patients with CrCl 30 mL/min and 40-60 mL/min.

Please see additional Important Safety Information on the right panel and the full prescribing information available at www.achaogen.com.



For adult patients with cUTI, including pyelonephritis, due to certain Enterobacteriaceae¹

To learn more about ZEMDRI, please speak with an Achaogen representative at this booth.

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Please see Indications and Important Safety Information, including BOXED WARNINGS, on adjacent panels and the full prescribing information available at www.achaogen.com.

IMPORTANT SAFETY INFORMATION

Additional Warnings and Precautions (continued)

Ototoxicity: Patients with ZEMDRI may be at increased risk of hearing loss, tinnitus, and/or vertigo. Symptoms of aminoglycoside-associated ototoxicity may be irreversible and may not become evident until after completion of therapy. Aminoglycoside-associated ototoxicity has been observed primarily in patients with a family history of hearing loss (including age-related hearing loss), patients with renal impairment, and in patients receiving higher doses and/or for longer periods than recommended. The benefit-risk of ZEMDRI therapy should be considered in these patients.

Neuromuscular Blockade: Aminoglycosides have been associated with exacerbation of muscle weakness in patients with underlying neuromuscular disorders, or delay in recovery of neuromuscular function in patients receiving concomitant neuromuscular blocking agents. During therapy with ZEMDRI, monitor for adverse reactions associated with neuromuscular blockade, particularly in high-risk patients, such as patients with underlying neuromuscular disorders (including myasthenia gravis) or those patients concomitantly receiving neuromuscular blocking agents.

Fetal Harm: Aminoglycosides, including ZEMDRI, can cause fetal harm when administered to a pregnant woman. Patients who use ZEMDRI during pregnancy or become pregnant while using ZEMDRI should be apprised of the potential hazard to the fetus.

Hypersensitivity Reactions: Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients receiving aminoglycoside antibiotic drugs. Before therapy with ZEMDRI is initiated, careful inquiry should be made of previous hypersensitivity reactions to other aminoglycosides should be made. Discontinue ZEMDRI if an allergic reaction occurs.

Clostridium difficile-Associated Diarrhea (CDAD): Reported for nearly all systemic antibiotic drugs and may range in severity from mild diarrhea to fatal colitis. Treatment with antibiogram drugs should be withheld until the cause and may cause associated toxicity has been determined. If the cause is not determined, CDAD is suspected or confirmed, antibiogram drugs should be discontinued. CDAD may need to be re-treated.

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

The most common adverse reactions (≥10% of patients treated with ZEMDRI) are decreased renal function, diarrhea, hypotension, headache, nausea, vomiting, and hypokalemia.

Please see the full prescribing information, including BOXED WARNINGS, for additional important safety information.

You may report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Achaogen at (833) AKAQ-802.

Reference: 1. ZEMDRI (plazomicin) [injection], North San Francisco, CA: Achaogen, Inc.; 2016.

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