

Zemdri[™] (plazomicin) – New drug approval

- On June 25, 2018, the <u>FDA approved</u> Achaogen's <u>Zemdri (plazomicin)</u>, for the treatment of patients 18 years of age or older with complicated urinary tract infections (cUTI), including pyelonephritis caused by the following susceptible microorganism(s): *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.
- Zemdri is the first once-daily aminoglycoside antibiotic approved for cUTI treatment of various Enterobacteriaceae resistant organisms.
- The efficacy of Zemdri was demonstrated in a noninferiority trial enrolling 609 adult patients
 hospitalized with cUTI. Patients received Zemdri or meropenem. The co-primary efficacy endpoints
 were composite cure (clinical cure and microbiological eradication) at day 5 and at test-of-cure
 (TOC) visit (day 17 ± 2).
 - At day 5, composite cure was 88% in the Zemdri group vs. 91.4% in the meropenem group (treatment difference = -3.4 [95% CI: -10.0, 3.1]).
 - At TOC visit, composite cure was 81.7% in the Zemdri group vs. 70.1% in the meropenem group (treatment difference = 11.6 [95% CI: 2.7, 20.3]).
- Zemdri carries a boxed warning for nephrotoxicity, ototoxicity, neuromuscular blockade and fetal harm.
- Warnings and precautions of Zemdri include hypersensitivity reactions, Clostridium difficileassociated diarrhea, and development of drug-resistant bacteria.
- The most common adverse reactions (≥ 1%) with Zemdri use were decreased renal function, diarrhea, hypertension, headache, nausea, vomiting and hypotension.
- The recommended dosage of Zemdri is 15 mg/kg administered every 24 hours by intravenous (IV) infusion over 30 minutes for 4 − 7 days in patients ≥ 18 years of age with a creatinine clearance ≥ 90 mL/min.
 - An appropriate oral therapy may be considered after 4 7 days of Zemdri therapy to complete a total duration of 7 - 10 days (IV plus oral). The maximum duration of Zemdri for cUTI is 7 days.
 - Consult the Zemdri drug label for dosing in patients with renal impairment.
- Achaogen's launch plans for Zemdri are pending. Zemdri will be available as a 500 mg/10 mL injection in a single-dose vial.



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