ZEMDRI®
(plazomicin) Injection

presented by
Noor Abd Allah Kadeem
PhD. Student

Pharmacology and toxicology department

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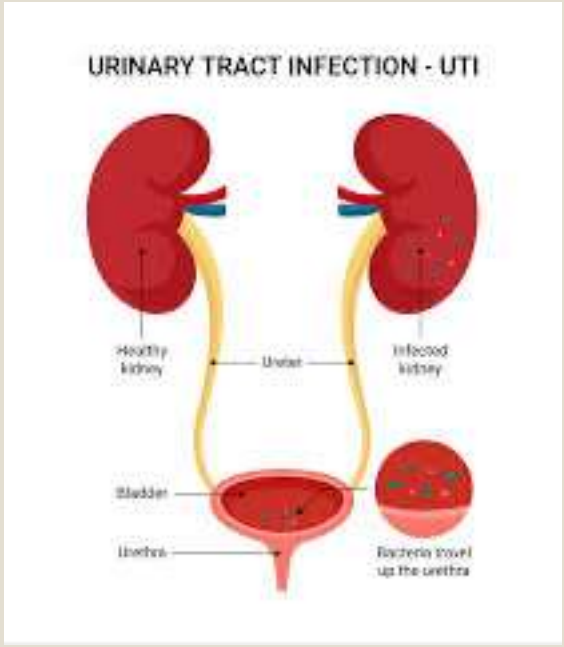
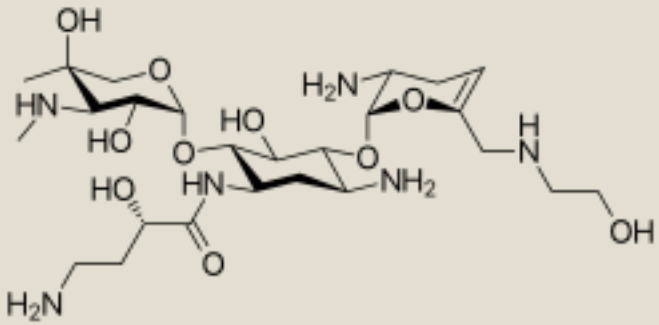
Plazomicin Injection:-

- A Next-Generation Aminoglycoside
- • Subtitle:
- Overview.
- Mechanism.
- Uses.
- Safety
- And Comparative Susceptibility of Aminoglycosides



Introduction to Plazomicin

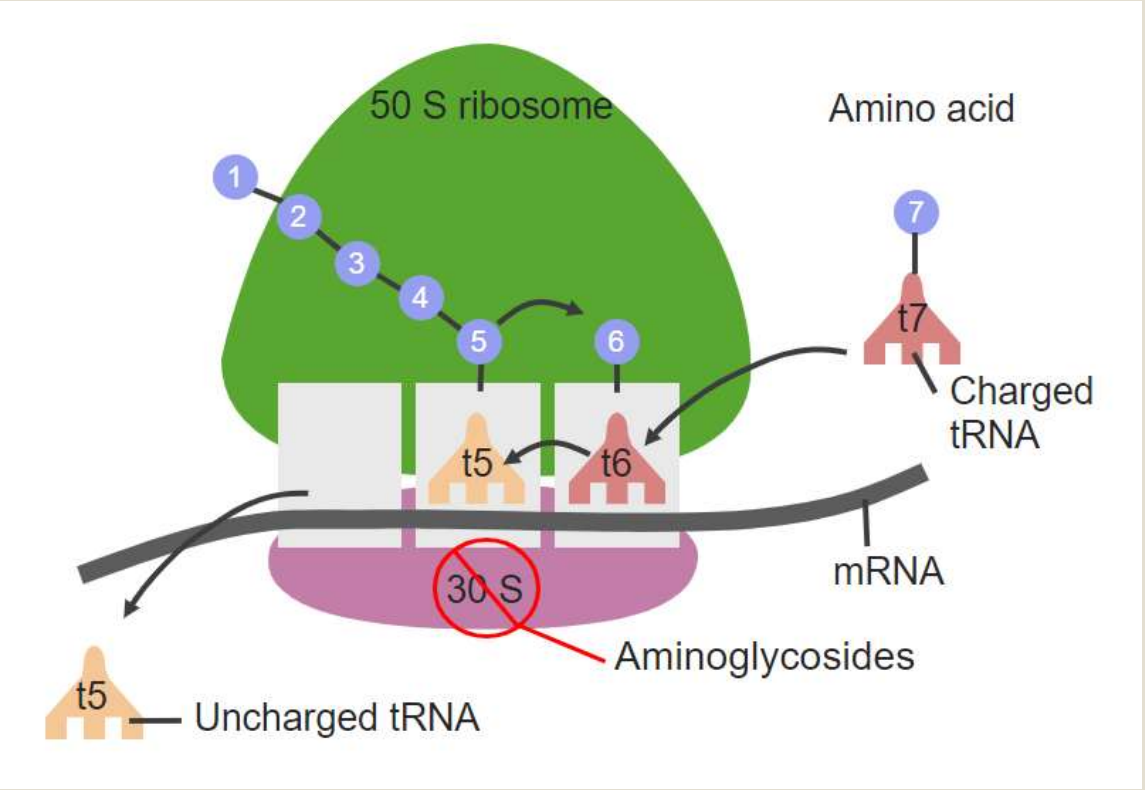
- Plazomicin, a next-generation aminoglycoside antibiotic, exhibits potent in vitro activity against multidrug-resistant Gram-negative bacteria, particularly carbapenem-resistant Enterobacteriaceae (CRE). Its structural modifications render it less susceptible to common aminoglycoside-modifying enzymes (AMEs), enhancing its efficacy where traditional aminoglycosides may lacks activity against *Enterococcus* spp., *Streptococcus*spp., *Stenotro phamonas maltophilia*, and obligate anaerobes.



Chemical structure of Plazomicin

Mechanism of Action

- Plazomicin exerts its effect by binding to the 30S portion of the bacterial ribosome, thereby inhibiting bacterial protein synthesis in a bactericidal manner
- • Bactericidal activity



Symptoms of a Urinary Tract Infection (UTI).

Problems peeing.

Fever.

Chills.

Cloudy, foul-smelling and/or dark pee.

Pain in your flank, abdomen, pelvic area or lower back.

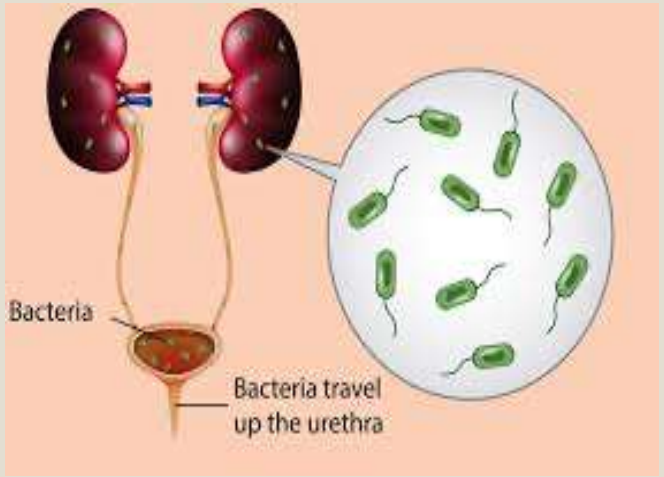
Pain while peeing.

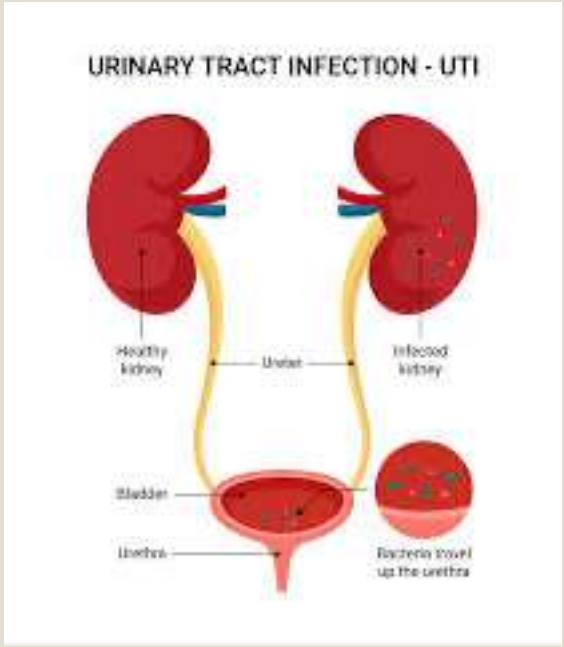
Pain during sex.

Cleveland Clinic

Indications and Usage

- • Treatment of complicated urinary tract infections (cUTIs)
- A complicated urinary tract infection (UTI) is an infection with a higher risk of treatment failure.
- these infections often require longer treatment durations, alternative antibiotics, and sometimes additional diagnostic evaluations to ensure effective mana
- • Used when other options are limited



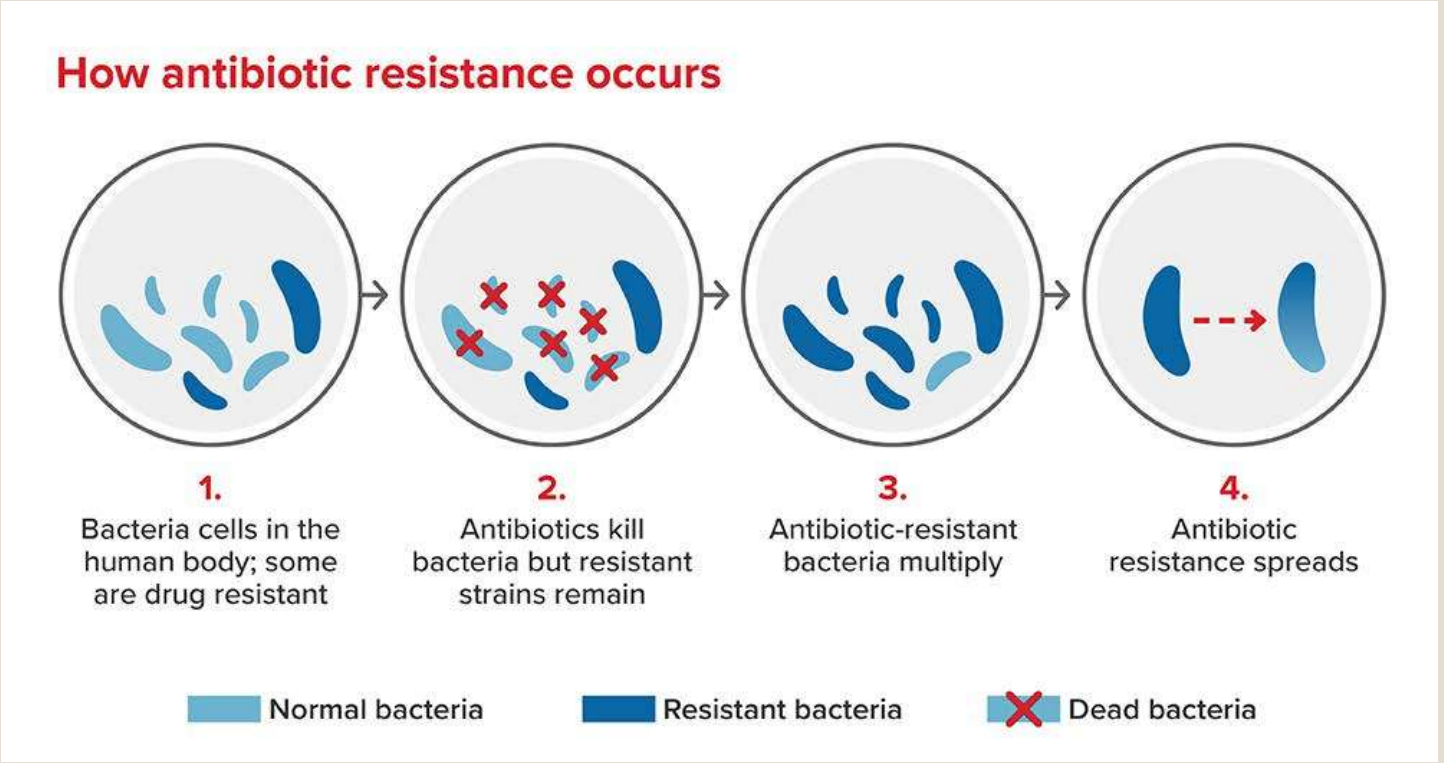


Plazomicin (Zemdri) — Approved Use in cUTIs

Parameter	Details
Indication	Treatment of adults with cUTIs, including pyelonephritis, caused by susceptible Enterobacteriaceae
Dosage	15 mg/kg administered intravenously once daily
Duration	7 to 10 days
Patient Population	Adults (≥18 years) with limited or no alternative treatment options
Common Pathogens	Multidrug-resistant Enterobacteriaceae, including ESBL-producing strains
Approval Date	June 25, 2018
Manufacturer	Achaogen, Inc.
FDA Approval Basis	Noninferiority to meropenem in clinical trials
Key Clinical Trial	EPIC study (NCT02486627)

Spectrum of Activity

- Active against multidrug-resistant Enterobacteriaceae
- Not effective against Pseudomonas or anaerobes



Dosage and Administration

- IV injection infused over 30 minutes

  typically once daily

◦ IV Preparation

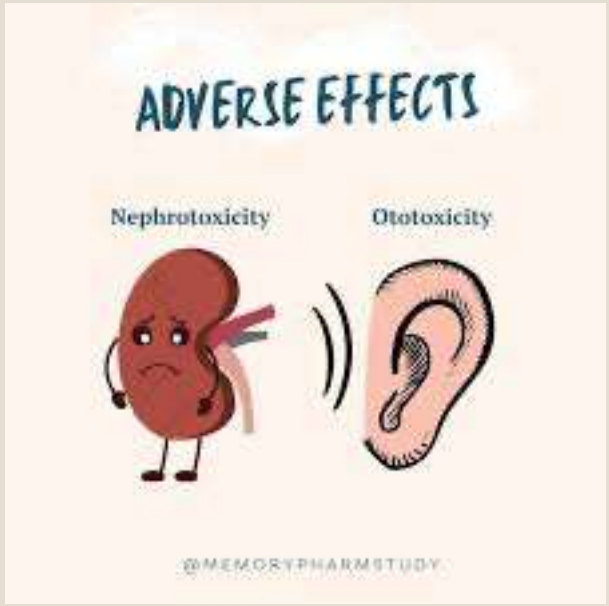
◦ Dilute an appropriate volume of plazomicin in 0.9% NaCl or lactated Ringer solution to achieve a final volume of 50 mL for IV infusion (final concentration: 2.5-45 mg/mL)

- Dose adjusted based on renal function

Estimated CrCl (mL/min)	Dosage[b]	Dosing interval
≥60 to <90	**15 mg/kg**	Every 24 hours
≥30 to <60	**10 mg/kg**	Every 24 hours
≥15 to <30	**10 mg/kg**	Every 48 hours

Side Effects and Warnings

- **Common side effects:**
  - Nausea.
  - headache.
  - Vomiting.
- **Serious side effect:-**
  - Nephrotoxicity
  - ototoxicity
  - Neuromuscular blockade [including myasthenia gravis
  - Pregnancy Aminoglycosides, including plazomicin, can cause fetal harm when administered to a pregnant woman



Adverse reaction	ZEMDRI (N=303), % (n)	Meropenem[a] (N=301), % (n)
Decreased renal function[b]	3.6% (11)	1.3% (4)
Diarrhea	2.3% (7)	1.7% (5)
Hypertension	2.3% (7)	2.3% (7)
Headache	1.3% (4)	3.0% (9)
Nausea	1.3% (4)	1.3% (4)
Vomiting	1.3% (4)	1.0% (3)
Hypotension	1.0% (3)	0.7% (2)

Comparison with Other Antibiotics

- **Comparative Susceptibility of Aminoglycosides**
- A study evaluating 303 multidrug-resistant Enterobacterales isolates assessed the susceptibility of various aminoglycosides using FDA breakpoints:
- • **Plazomicin (PLZ):** 80.2% susceptible
- • **Amikacin (AMK):** 59.1% susceptible
- • **Gentamicin (GEN):** 41.6% susceptible
- • **Tobramycin (TOB):** 16.5% susceptible
- These findings indicate that plazomicin had the highest overall susceptibility rate among the tested aminoglycosides


Thank
you!