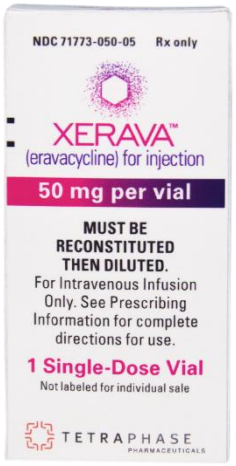
Xerava (eravacycline)



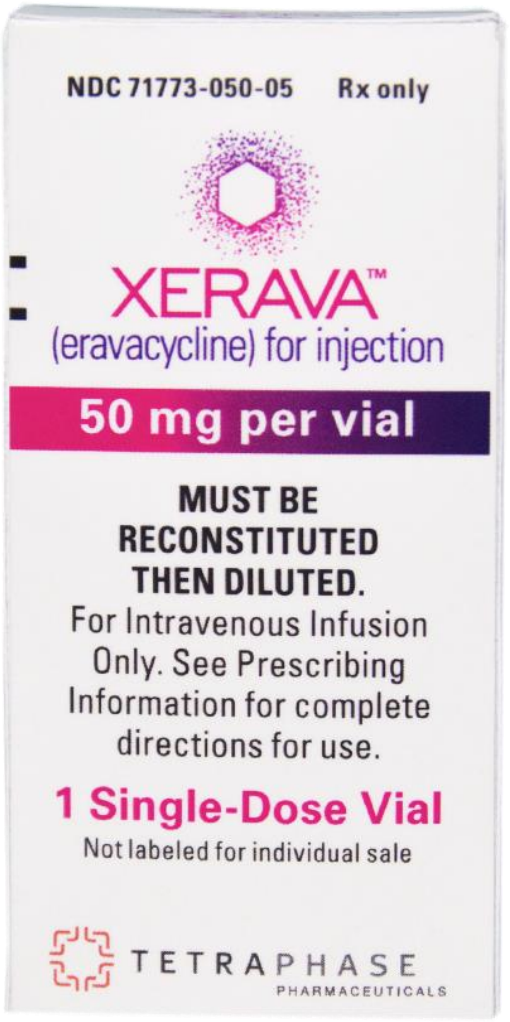
NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Xerava
- **Generic name:** Eravacycline
- **Pharmacological class:** Tetracycline antibiotic
- **Strength and Formulation:** 50mg; per vial; lyophilized powder for IV infusion after reconstitution and dilution; preservative-free
- **Manufacturer:** Tetraphase Pharmaceuticals
- **How supplied:** Single-dose vials—1, 12
- **Legal Classification:** Rx

Xerava


NDC 71773-050-05 Rx only
XERAVA™
(eravacycline) for injection
50 mg per vial
MUST BE RECONSTITUTED THEN DILUTED.
For Intravenous Infusion Only. See Prescribing Information for complete directions for use.
1 Single-Dose Vial
Not labeled for individual sale
TETRAPHASE
PHARMACEUTICALS

Indication

- Tetracycline-susceptible complicated intra-abdominal infections (cIAI) in patients ≥18yrs of age

Limitations of Use

- Not for the treatment of complicated urinary tract infections (cUTI)

Dosage & Administration

- Give by IV infusion over 60mins
- **≥18yrs:** 1mg/kg every 12hrs for 4–14 days

Dosage & Administration

- **Severe hepatic impairment (Child Pugh C):** 1mg/kg every 12hrs on Day 1, then 1mg/kg every 24hrs starting on Day 2 for a total duration of 4–14 days
- **Concomitant strong CYP3A inducers:** 1.5mg/kg every 12hrs for a total duration of 4–14 days

Considerations for Special Populations

- **Pregnancy:** 2nd & 3rd trimester: may cause permanent discoloration of the teeth or reversible inhibition of bone growth
- **Nursing mothers:** Not recommended (during and for 4 days after the last dose)
- **Pediatric:** <8yrs: not recommended
- **Hepatic impairment:** Severe: adjust dose (see Dosing & Administration)

Warnings/Precautions

- **Discontinue** if allergic reaction or superinfection occurs
- Evaluate if diarrhea occurs; discontinue if *C. difficile*-associated diarrhea is suspected or confirmed

Interactions

- May be antagonized by strong **CYP3A inducers**; increase dose (see Dosing & Administration)
- May need to reduce concomitant **anticoagulant** dose

Adverse Reactions

- Infusion site reactions
- Nausea
- Vomiting
- Diarrhea
- Hypotension
- Wound dehiscence
- Hypersensitivity reactions
- Tooth discoloration
- Enamel hypoplasia
- Inhibition of bone growth (up to 8yrs of age)
- *C. diff*-associated diarrhea
- Photosensitivity
- Pseudotumor cerebri
- Increased BUN
- Azotemia
- Acidosis
- Hyperphosphatemia
- Pancreatitis
- Abnormal liver function tests

Mechanism of Action

- Eravacycline is a fluorocycline antibacterial within the tetracycline class of antibacterial drugs
- It disrupts bacterial protein synthesis by binding to the 30S ribosomal subunit thus preventing the incorporation of amino acid residues into elongating peptide chains

Clinical Studies

- Xerava was evaluated in two Phase 3, randomized, double-blind, active-controlled, multinational, multicenter trials **(Trial 1** and **Trial 2)** in hospitalized cIAI adults with at least 1 baseline intra-abdominal pathogen (N=846)

Clinical Studies

- In **Trial 1**, patients were randomized to Xerava 1mg/kg every 12hrs (N=220) or ertapenem 1g every 24hrs (N=226)
- In **Trial 2**, patients were randomized to Xerava 1mg/kg every 12hrs (N=195) or meropenem 1g every 8hrs (N=205)

Clinical Studies

- **Clinical cure** was defined as complete resolution or significant improvement of signs or symptoms of the index infection at the Test of Cure (TOC) visit which occurred 25 to 31 days after randomization

Clinical Studies

- In **Trial 1**, the clinical cure rate was **86.8%** for the Xerava group vs **87.6%** for the ertapenem group
- Mean difference -0.80% (95% CI, -7.1 to 5.5)

Clinical Studies

- In **Trial 2**, the clinical cure rate was **90.8%** for the Xerava group vs **91.2%** for the meropenem group
- Mean difference -0.5% (95% CI, -6.3 to 5.3)

- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

  https://www.empr.com/xerava/drug/34883/