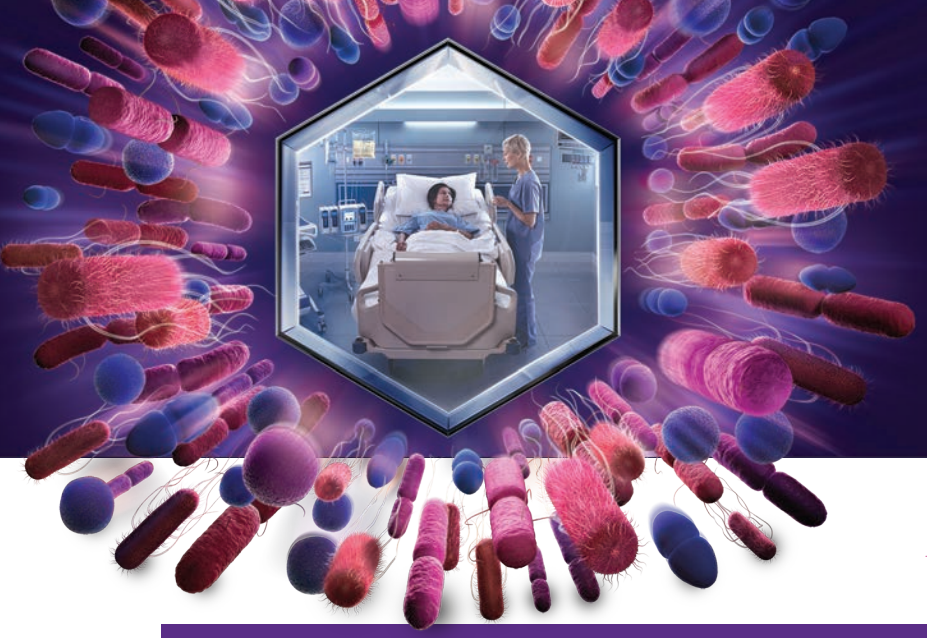

In patients with cIAI...

WHEN THE RESISTANCE RISK IS HIGH,

CHOOSE WITH CONFIDENCE

XERAVA®
(eravacycline) for injection

Product information for XERAVA® (eravacycline) for injection[1]

How Supplied	XERAVA (eravacycline) for injection is a yellow to orange, sterile, preservative-free powder for reconstitution in single-dose, 10-mL, clear glass vials with a rubber stopper and an aluminum overseal.
Dose Forms and Strengths	XERAVA is available in 50-mg and 100-mg single-dose vials • 50 mg of eravacycline (equivalent to 63.5 mg eravacycline dihydrochloride) • 100 mg of eravacycline (equivalent to 127 mg eravacycline dihydrochloride)
Package Configuration	• Twelve-vial carton containing twelve 50-mg single-dose–vial cartons • Twelve-vial carton containing twelve 100-mg single-dose–vial cartons (in shrink-wrap packaging)
NDC Numbers	• 50-mg 12-vial carton containing 12 single-dose vials: NDC 71773-050-12 • 100-mg 12-vial carton containing 12 single-dose vials (in shrink-wrap packaging): NDC 71773-100-12
Storage	Prior to reconstitution, XERAVA should be stored at 2 °C to 8 °C (36 °F to 46 °F). Keep vial in carton until use. The diluted solutions must be infused within 24 hours if stored at room temperature (not to exceed 25 °C/77 °F) or within 10 days if stored refrigerated at 2 °C to 8 °C (36 °F to 46 °F). Reconstituted XERAVA solutions and diluted XERAVA infusion solutions should not be frozen.

Specialty distributors for XERAVA

Cardinal Health Specialty Pharmaceutical Distribution: 1-866-677-4844

Morris & Dickson Co., L.L.C.: 1-800-388-3833

McKesson Specialty Health: 1-800-482-6700

McKesson Plasma and Biologics: 1-877-625-2566

ASD Healthcare (AmerisourceBergen): 1-800-746-6273

Besse Medical: 1-513-851-2345

WAC

$57.00/50-mg vial, available in a 12-vial carton
$102.00/100-mg vial, available in a 12-vial carton

PHS and FSS pricing available.

Indications and Usage

XERAVA is indicated for the treatment of complicated intra-abdominal infections (cIAI) caused by susceptible microorganisms: *Escherichia coli*, *Klebsiella pneumoniae*, *Citrobacter freundii*, *Enterobacter cloacae*, *Klebsiella oxytoca*, *Enterococcus faecalis*, *Enterococcus faecium*, *Staphylococcus aureus*, *Streptococcus anginosus* group, *Clostridium perfringens*, *Bacteroides* species, and *Parabacteroides distasonis* in patients 18 years or older.

Limitations of Use

XERAVA is not indicated for the treatment of complicated urinary tract infections (cUTI).

Usage

To reduce the development of drug-resistant bacteria and maintain the effectiveness of XERAVA and other antibacterial drugs, XERAVA should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

Please see Important Safety Information on subsequent pages and full Prescribing Information.

Learn more at xerava.com.

Dosage and administration for adult patients (≥18 years of age) with cIAI[1]

Administer **1 mg/kg*** ▶ **Every** **12 hours** by IV infusion ▶ **Over approximately** **60 minutes**

The recommended duration of treatment is **4 to 14 days**. The duration of therapy should be guided by the severity and location of infection and the patient's clinical response.

*Calculate the dose of XERAVA based on the patient's weight: 1 mg/kg of actual body weight.

No dosage adjustment is necessary in patients with renal impairment[1]

No dosage adjustment is necessary in patients with mild to moderate hepatic impairment (Child Pugh A and Child Pugh B)[1]

Adjust XERAVA dosage in patients with severe hepatic impairment (Child Pugh C)[1]

- Administer XERAVA **1 mg/kg** every **12 hours** on Day 1 followed by XERAVA **1 mg/kg** every **24 hours** starting on Day 2 for a total duration of **4 to 14 days**

No dosage adjustment is warranted in patients with concomitant use of a weak or moderate cytochrome P450 isoenzymes (CYP)3A inducer[1]

Dosage modifications for patients with concomitant use of a strong CYP3A inducer[1]

- Administer XERAVA **1.5 mg/kg** every **12 hours** for a total duration of **4 to 14 days**

No therapeutic drug monitoring required[1]

cIAI, complicated intra-abdominal infection; IV, intravenous.

IMPORTANT SAFETY INFORMATION

XERAVA is contraindicated for use in patients with known hypersensitivity to eravacycline, tetracycline-class antibacterial drugs, or to any of the excipients. Life-threatening hypersensitivity (anaphylactic) reactions have been reported with XERAVA.

The use of XERAVA during tooth development (last half of pregnancy, infancy and childhood to the age of 8 years) may cause permanent discoloration of the teeth (yellow-gray-brown) and enamel hypoplasia.

The use of XERAVA during the second and third trimester of pregnancy, infancy and childhood up to the age of 8 years may cause reversible inhibition of bone growth.

Clostridium 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.

The most common adverse reactions observed in clinical trials (incidence ≥3%) were infusion site reactions (7.7%), nausea (6.5%), and vomiting (3.7%).

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Please see Indications and Usage on previous page, additional Important Safety Information on following page, and full Prescribing Information.

Learn more at xerava.com.

Preparation and Administration[1]

XERAVA is for intravenous infusion only. Each vial is for single use only.

Preparation

XERAVA is supplied as a sterile, yellow to orange, dry powder in a single-dose vial that must be reconstituted and further diluted prior to intravenous infusion as outlined below. XERAVA does not contain preservatives. Aseptic technique must be used for reconstitution and dilution as follows:

1. Calculate the dose of XERAVA based on the patient weight; 1 mg/kg of actual body weight. Prepare the required dose for intravenous infusion by reconstituting the appropriate number of vials needed. Reconstitute each vial of XERAVA with 5 mL of Sterile Water for injection, USP or with 5 mL of 0.9% Sodium Chloride Injection, USP, which will deliver the following:

   a. XERAVA 50-mg vial will deliver 50 mg (10 mg/mL) of eravacycline (free-base equivalents).
   b. XERAVA 100-mg vial will deliver 100 mg (20 mg/mL) of eravacycline (free-base equivalents).

2. Swirl the vial gently until the powder has dissolved entirely. Avoid shaking or rapid movement as it may cause foaming. The reconstituted XERAVA solution should be a clear, pale yellow to orange solution. Do not use the solution if you notice any particles or the solution is cloudy. Reconstituted solution is not for direct injection. The stability of the solution after reconstitution in the vial has been demonstrated for 1 hour at room temperature (not to exceed 25 °C/77 °F). If the reconstituted solution in the vial is not diluted in the infusion bag within 1 hour, the reconstituted vial content must be discarded.

3. The reconstituted XERAVA solution is further diluted for intravenous infusion to a target concentration of 0.3 mg/mL in a 0.9% Sodium Chloride Injection, USP infusion bag before intravenous infusion. To dilute the reconstituted solution, withdraw the full or partial reconstituted vial content from each vial and add it into the infusion bag to generate an infusion solution with a target concentration of 0.3 mg/mL (within a range of 0.2 to 0.6 mg/mL). Do not shake the bag.

4. The diluted solutions must be infused within 24 hours if stored at room temperature (not to exceed 25 °C/77 °F) or within 10 days if stored refrigerated at 2 °C to 8 °C (36 °F to 46 °F). Reconstituted XERAVA solutions and diluted XERAVA infusion solutions should not be frozen.

5. Visually inspect the diluted XERAVA solution for particulate matter and discoloration prior to administration (the XERAVA infusion solution for administration is clear and ranges from light yellow to orange). Discard unused portions of the reconstituted and diluted solution.

Administration of the Intravenous Infusion

The diluted XERAVA solution is administered as an intravenous infusion over approximately 60 minutes.

XERAVA may be administered intravenously through a dedicated line or through a Y-site. If the same intravenous line is used for sequential infusion of several drugs, the line should be flushed before and after infusion of XERAVA with 0.9% Sodium Chloride Injection, USP.

IMPORTANT SAFETY INFORMATION (cont'd)

XERAVA is structurally similar to tetracycline-class antibacterial drugs and may have similar adverse reactions. Adverse reactions including photosensitivity, pseudotumor cerebri, and anti-anabolic action which has led to increased BUN, azotemia, acidosis, hyperphosphatemia, pancreatitis, and abnormal liver function tests, have been reported for other tetracycline-class antibacterial drugs, and may occur with XERAVA. Discontinue XERAVA if any of these adverse reactions are suspected.

To report SUSPECTED ADVERSE REACTIONS, contact Tetraphase Pharmaceuticals Inc., at 1-833-7-XERAVA (1-833-793-7282) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see accompanying full Prescribing Information.

Reference: 1. XERAVA. Prescribing information. Tetraphase Pharmaceuticals, Inc.; Rev. 07/2021.

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