

Dosage and Administration for Adult Patients (≥18 Years of Age) With cIAI¹

Administer Every Over approximately

1 mg/kg > 12 hours > 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.

by IV infusion

No dosage adjustment is necessary for XERAVA in patients with renal impairment¹

No dosage adjustment is warranted for XERAVA in patients with mild to moderate hepatic impairment (Child Pugh A and Child Pugh B)¹

See reverse side for dosage adjustments in special patient populations.

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.

<u>Limitations of Use</u>

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

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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.

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



Learn more at xerava.com.

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

Dosage modifications for patients with concomitant use of a strong cytochrome P450 isoenzymes (CYP)3A inducer¹

- Administer XERAVA 1.5 mg/kg every 12 hours for a total duration of 4 to 14 days
- No dosage adjustment is warranted in patients with concomitant use of a weak or moderate CYP3A inducer

Important Safety Information

XERAVA is contraindicated for use in patients with known hypersensitivity to eravacycline or to tetracycline-class antibacterial drugs. 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%).

XERAVA is structurally similar to tetracycline-class antibacterial drugs and may have similar adverse reactions. Adverse reactions including photosensitivity, pseudotumor cerebri, and antianabolic 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 full Prescribing Information for XERAVA at XERAVA.com.

Reference: 1. XERAVA [prescribing information]. Watertown, MA: Tetraphase Pharmaceuticals, Inc.; 2018.

Please see reverse side for Indications and Usage and <u>accompanying full Prescribing Information</u>.





