Delafloxacin (Baxdela™)

PO and IV Only

Use requires formal ID Consult

Fluoroquinolone antibiotic with FDA-approval for acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible bacteria in adults.

<u>Activity</u>: Coverage against gram-positive organisms (eg. *Staphylococcus aureus* (MRSA and MSSA), *Streptococcus spp.*, and *Enterococcus faecalis*), gram-negative organisms (eg. *Escherichia coli, Enterobacter cloacae, Klebsiella pneumoniae*, and *Pseudomonas aeruginosa*. Also covers some anaerobes and atypical respiratory tract pathogens.

Criteria for use:

• Treatment of adult patients with ABSSSI caused by susceptible organisms when unable to use any other agents (refer to empiric therapy for ABSSSI)

Unacceptable Uses:

- Patients with ESRD (eg. hemodialysis) or eGFR < 15 mL/min/1.73m², PO or IV delafloxacin use not recommended due to insufficient information
- Contraindicated in patients with known hypersensitivity to delafloxacin or any agents in the fluoroquinolone class of antibiotics

Dosing in Adults:

- Standard: 300 mg <u>IV</u> over 60 min Q12H, or 450 mg <u>PO</u> Q12H
- Renal impairment dose adjustments: (based on eGFR <u>NOT</u> CrCl)

 eGFR 15-29 mL/min/1.73m² 200 mg Q12H IV (<u>NOT for PO</u>)
 - eGFR < 15 mL/min/1.73m² NOT RECOMMENDED for both IV and PO
- Treatment duration ranges from 5 to 14 days
- Oral formulation may be given with or without food, but must be spaced with any multivalent cations (eg. Ca²⁺, Mg²⁺) 2 hours before and 6 hours after dose

Monitoring:

• SCr/BUN (particularly in patients with underlying renal dysfunction)

Considerations for Use:

- Unlike other fluoroquinolones, delafloxacin does <u>not</u> appear to have a risk of photosensitivity or QTc prolongation.
- Assess for potential drug-drug interactions
- Intravenous delafloxacin is formulated with sulfobutylether-βcyclodextrin vehicle, which may accumulate in patients with severe renal dysfunction (see above dose adjustment recommendations).
- <u>Black box warning</u>: Fluoroquinolones have been associated with tendinitis and tendon rupture, peripheral neuropathy, and central nervous system (CNS) effects. Avoid use in patients with history/current myasthenia gravis, tendinitis or tendon rupture, and peripheral neuropathy.

ABSSSI= acute bacterial skin and skin structure infections; BUN= blood urea nitrogen; Ca²⁺= calcium; CrCl= Creatinine Clearance; ESRD= end-stage renal disease; eGFR= estimated glomerular filtration rate; FDA= Food and Drug Administration; H= hour(s); ID= infectious diseases; IV= Intravenous; m= meters; Mg²⁺= magnesium; MRSA=methicillin-resistant *Staphylococcus aureus;* MSSA= methicillin-susceptible *Staphylococcus aureus;* PO= Oral; Q= every; SCr= serum creatinine

References: Baxdela (Delafloxacin) [package insert]. Melinta Therapeutics, Inc; Lincolnshire (II): June 2017.