**Available Susceptibility Testing for Baxdela**

Baxdela is indicated in adults for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible isolates of the following:

**Gram-positive organisms:** Staphylococcus aureus (including methicillin-resistant [MRSA] and methicillin susceptible [MSSA] isolates), Staphylococcus haemolyticus, Staphylococcus lugdunensis, Streptococcus agalactiae, Streptococcus anginosus Group (including Streptococcus anginosus, Streptococcus intermedius, and Streptococcus constellatus), Streptococcus pyogenes, and Enterococcus faecalis.

**Gram-negative organisms:** Escherichia coli, Enterobacter cloacae, Klebsiella pneumoniae, and Pseudomonas aeruginosa.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Baxdela and other antibacterial drugs, Baxdela should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria.

**SELECTED IMPORTANT SAFETY INFORMATION:**

**WARNING:** SERIOUS ADVERSE REACTIONS INCLUDING TENDINITIS, TENDON RUPTURE, PERIPHERAL NEUROPATHY, CENTRAL NERVOUS SYSTEM EFFECTS, AND EXACERBATION OF MYASTHENIA GRAVIS

Fluoroquinolones have been associated with disabling and potentially irreversible serious adverse reactions that have occurred together, including:

- Tendinitis and tendon rupture
- Peripheral neuropathy
- Central nervous system effects

Discontinue BAXDELA immediately and avoid the use of fluoroquinolones, including BAXDELA, in patients who experience any of these serious adverse reactions.

Fluoroquinolones may exacerbate muscle weakness in patients with myasthenia gravis. Avoid BAXDELA in patients with known history of myasthenia gravis.

Please see other side for full Important Safety Information. Please see full Prescribing Information, including Boxed Warning, and the Patient Medication Guide.
**BAXDELA INDICATION & USAGE:**

BAXDELA is indicated in adults for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible isolates of the following:

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- **Gram-negative organisms:** Escherichia coli, Enterobacter cloacae, Klebsiella pneumoniae, and Pseudomonas aeruginosa.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of BAXDELA and other antibacterial drugs, BAXDELA should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria.

**IMPORTANT SAFETY INFORMATION:**

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**Contraindications**

BAXDELA is contraindicated in patients with known hypersensitivity to BAXDELA or other fluoroquinolones.

**Warnings and Precautions**

Fluoroquinolones have been associated with disabling and potentially irreversible serious adverse reactions. Avoid use in patients who have experienced any of the following serious adverse reactions. If these reactions occur in patients receiving BAXDELA, discontinue BAXDELA immediately and institute appropriate treatment:

- Tendinitis, tendon rupture, with increased risk in elderly, patients taking corticosteroids and in patients with organ transplants
- Peripheral neuropathy, such as pain, burning, tingling, numbness, and/or weakness or other alterations of sensation in touch and/or motor strength

- Psychiatric adverse reactions, such as toxic psychosis; hallucinations, or paranoia; depression, or suicidal thoughts or acts; delirium, disorientation, confusion, or disturbances in attention; anxiety, agitation, or nervousness; insomnia or nightmares; memory impairment
- Central nervous system adverse reactions such as seizures, increased intracranial pressure, dizziness, and tremors
- Exacerbation of myasthenia gravis, including death and requirement for ventilator

Hypersensitivity reactions have been reported in patients receiving fluoroquinolones, including BAXDELA. Reactions can be serious and occasionally fatal (anaphylactic). Discontinue BAXDELA at the first sign of hypersensitivity.

Clostridium difficile-associated diarrhea has been reported with nearly all systemic antibacterial agents, including BAXDELA, with severity ranging from mild diarrhea to fatal colitis. Evaluate if diarrhea occurs.

Fluoroquinolones have been associated with an increased risk of aortic aneurysm and dissection, especially in elderly patients. In patients with a known aortic aneurysm or who are at greater risk for aortic aneurysms, reserve BAXDELA for use only when there are no alternative antibacterial treatments available.

Prescribing BAXDELA in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

Fluoroquinolones have been associated with disturbances of blood glucose, including symptomatic hyperglycemia and hypoglycemia. Severe cases of hypoglycemia resulting in coma or death have been reported with other fluoroquinolones. Monitor blood glucose carefully in diabetic patients receiving oral hypoglycemic agents or insulin.

Discontinue BAXDELA and initiate appropriate therapy immediately if a hypoglycemic reaction occurs.

**Adverse Reactions**

The most common adverse reactions in patients treated with BAXDELA were nausea (8%), diarrhea (8%), headache (3%), transaminase elevations (3%), and vomiting (2%).

**Use in Specific Populations**

In patients with severe renal impairment (eGFR of 15-29 mL/min/1.73 m²), the dosage of BAXDELA should be decreased to 200 mg IV every 12 hours or 450 mg orally every 12 hours. BAXDELA is not recommended in patients with End Stage Renal Disease (ESRD) (eGFR of <15 mL/min/1.73 m², including hemodialysis) due to insufficient information to provide dosing recommendations.

Please see full Prescribing Information, including Boxed Warning, and the Patient Medication Guide.