Available Susceptibility Testing for Baxdela™ (delafloxacin)

450 mg tablets
300 mg vial for injection

Delafloxacin Susceptibility Disk Available from Hardy Diagnostics

Ordering Information:

- Available in single pack (Order Number: Z9301)
- Compatible with BD dispenser

For in vitro diagnostic use only. Observe approved biohazard precautions and aseptic techniques. This product is to be used only by adequately trained and qualified laboratory personnel. Sterilize all biohazard waste before disposal.

Photo Credit: Hardy Diagnostics

FDA-Cleared Susceptibility Test Interpretive Criteria for Delafloxacin

	Disk Diffusion (Zone Diameter in mm)		
Pathogen	**Susceptible**	**Intermediate**	**Resistant**
Staphylococcus aureus (methicillin-resistant and methicillin-susceptible isolates)	≥ 23	20-22	≤ 19
Staphylococcus haemolyticus	≥ 24	21-23	≤ 20
Streptococcus pyogenes[a]	≥ 20	-	-
Steptococcus agalactiae		-	
Streptococcus anginosus Group[a,b]	≥ 25	-	-
Enterococcus faecalis	≥ 21	19-20	≤ 18
Enterobacteriaceae[c]	≥ 22	19-21	≤ 18
Pseudomonas aeruginosa	≥ 23	20-22	≤ 19

a.The current absence of resistant isolates precludes defining any results other than "Susceptible."Isolates yielding MIC results other than "Susceptible" should be submitted to a reference laboratory for futher testing. **b.** includes: *S. anginosus, S. constellatus and S. intermedius.* **c.** *E. coli, K. pneumoniae,* and *E. cloacae only.*

Delafloxacin Microbroth Dilution Thermo Scientific™ Sensititre™ MIC Plates from Thermo Fisher Scientific

Ordering Information:

For more information, contact your local Thermo Fisher Scientific Microbiology representative at **microbiology@thermofisher.com** or visit **www.thermofisher.com/AST**

- Manual to fully automated plate reading
- True minimum inhibitory concentration (MIC) results

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Photo Credit: Thermo Fisher Scientific

FDA-Cleared Susceptibility Test Interpretive Criteria for Delafloxacin

	MIC (mcg/mL)		
Pathogen	**Susceptible**	**Intermediate**	**Resistant**
Staphylococcus aureus (methicillin-resistant and methicillin-susceptible isolates)	≤ 0.25	0.5	≥ 1
Staphylococcus haemolyticus	≤ 0.25	0.5	≥ 1
Streptococcus pyogenes[a]	≤ 0.06	-	-
Steptococcus agalactiae	≤ 0.06	0.12	≥ 0.25
Streptococcus anginosus Group[a,b]	≤ 0.06	-	-
Enterococcus faecalis	≤ 0.12	0.25	≥ 0.5
Enterobacteriaceae[c]	≤ 0.25	0.5	≥ 1
Pseudomonas aeruginosa	≤ 0.5	1	≥ 2

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Delafloxacin MIC Test Strip Available From Liofilchem

Ordering Information:

- US customers can place an order by phone: **781-902-0312** or e-mail: **orders@liofilchem.us**
- For more information, contact **liofilchem@liofilchem.net**

Description	µg/mL	Strips/Box	Order Number
Delafloxacin	0.002-32	10	920801
Delafloxacin	0.002-32	30	92080
Delafloxacin	0.002-32	100	920800

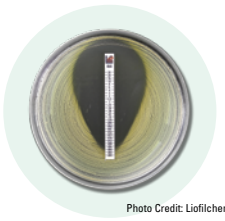

Photo Credit: Liofilchem

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INDICATION & USAGE:

BAXDELA is a fluoroquinolone antibacterial indicated in adults for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible bacteria.

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 ABSSSI that are proven or strongly suspected to be caused by 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 Important Safety Information. Please see full Prescribing Information, including **Boxed Warning** and the Patient Medication Guide.

Melinta THERAPEUTICS
The Antibiotics Company

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Contraindications

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

Warnings and Precautions

Risk of tendinitis, tendon rupture, peripheral neuropathy, and central nervous system effects is increased with use of fluoroquinolones. Discontinue BAXDELA immediately at the first signs or symptoms of any of these serious adverse reactions.

Avoid BAXDELA in patients with known history of myasthenia gravis.

Hypersensitivity reactions may occur after first or subsequent doses of BAXDELA. Discontinue BAXDELA at the first sign of hypersensitivity.

Clostridium difficile-associated diarrhea has been reported in users of nearly all systemic antibacterial drugs, including BAXDELA. Evaluate if diarrhea occurs.

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.

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 m^2), 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 m^2) due to insufficient information to provide dosing recommendations.

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

Baxdela™
(delafloxacin) 450 mg tablets
300 mg vial for injection

Melinta THERAPEUTICS
The Antibiotics Company

12/17 PP-BAX-US-0300 v1.0