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

FDA-Cleared Susceptibility Test Interpretive Criteria for Delafloxacin

For specific information regarding susceptibility test interpretive criteria and associated test methods and quality control standards recognized by FDA for this drug, please see: https://www.fda.gov/STIC

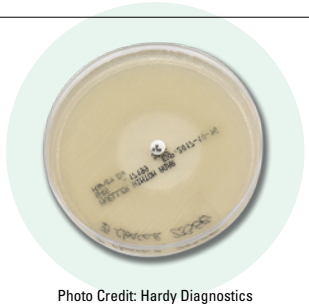

Photo Credit: Hardy Diagnostics

Delafloxacin Susceptibility Disk Available from Hardy Diagnostics

Ordering Information:

- Available in: 1-pack (Order Number: Z9301) and 5-pack (Order Number: Z9305)
- 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.

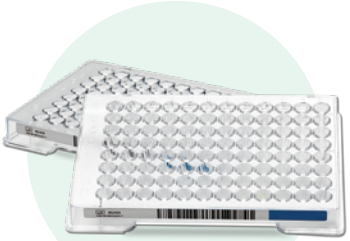

Photo Credit: Thermo Fisher Scientific

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

Related Products	Quantity	Part No.
Sensititre Delafloxacin DELAXN Plate	10/box	DELAXN

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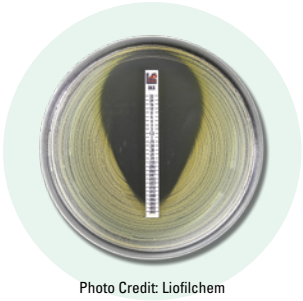

Photo Credit: Liofilchem

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

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INDICATIONS AND 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:

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 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. Ensure the Medication Guide is provided to your patients.

Melinta THERAPEUTICS

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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*.

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

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 see full Prescribing Information, including **Boxed Warning** and the Patient Medication Guide. Ensure the Medication Guide is provided to your patients.

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

Melinta THERAPEUTICS
The Antibiotics Company

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