Fetroja® – Resistant Isolate Program

This medical response contains information in addition to that provided in the Fetroja® (cefiderocol) for injection, for intravenous use Full Prescribing Information approved by the U.S. Food and Drug Administration (FDA). Shionogi does not recommend the use of Fetroja in any manner other than as described in the Full Prescribing Information. **Please see the accompanying Fetroja Full Prescribing Information**.

Summary | How the Resistant Isolate Program Works | How to Submit a Resistant Isolate | Relevant Prescribing Information | Abbreviations/ References

Summary

Shionogi offers a laboratory testing program for isolates that are identified as non-susceptible to cefiderocol[1]

- The Cefiderocol Resistant Isolate Program is administered through a third-party testing laboratory, International Health Management Associates (IHMA), with assistance from your MSL
- IHMA will provide antimicrobial susceptibility testing (broth microdilution) and whole genome sequencing (if needed) of the submitted isolates at no cost to the laboratory
- Please note this is educational in nature and not to be used for patient care

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How the Resistant Isolate Program Works

1. Your MSL will put you in contact with IHMA. IHMA will send a shipping kit for the isolate(s), which are then returned to IHMA via FedEx (FedEx tracking number is also provided)
2. IHMA conducts identification using MALDI-TOF and AST via broth microdilution with ID-CAMHB for cefiderocol and standard CAMHB for other agents tested
3. If the cefiderocol MIC values are >4 µg/mL for Enterobacterales, *Pseudomonas aeruginosa*, and *Acinetobacter baumannii* complex or >1 µg/mL for *Stenotrophomonas maltophilia* or other species:[1]
    a. WGS will be completed to evaluate the isolate(s) for:
        i. Chromosomal and extrachromosomal beta-lactamases
        ii. Single nucleotide polymorphisms (SNPs) in penicillin-binding protein 3 (*ftsI*)
        iii. SNPs in porin channels (*ompC*, *ompF*, *oprD*, *carO*)
        iv. SNPs in iron-transport related genes (*cirA*, *fiu*, *piuD*, *piuA/C*, *pirA*, *tonB*, *exbB*, *exbD*, *pvlS*)

When testing is complete, your MSL will share the data with your site:[1]
- **AST results take 1-2 weeks from the time IHMA receives the isolates**
- **For isolates that are resistant and undergo WGS, the results will take 1-2 months**

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How to Submit a Resistant Isolate

Submit a Medical Inquiry

If you need additional information, please contact Shionogi Medical Information at (800) 849-9707 or medinfo@shionogi.com

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Relevant Prescribing Information

Fetroja® is indicated in patients 18 years of age or older for the treatment of:[2]

- Complicated urinary tract infections (cUTIs), including pyelonephritis caused by the following susceptible Gram-negative microorganisms:
  - *Escherichia coli*
  - *Klebsiella pneumoniae*
  - *Proteus mirabilis*
  - *Pseudomonas aeruginosa*
  - *Enterobacter cloacae* complex
- Hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP), caused by the following susceptible Gram-negative microorganisms:
  - *Acinetobacter baumannii* complex
  - *Escherichia coli*
  - *Enterobacter cloacae* complex
  - *Klebsiella pneumoniae*
  - *Pseudomonas aeruginosa*
  - *Serratia marcescens*

Fetroja is contraindicated in:[2]

- Patients with a known history of severe hypersensitivity to cefiderocol or other beta-lactam antibacterial drugs, or any other component of **Fetroja**

Please see the accompanying **Fetroja Full Prescribing Information**

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Abbreviations

AST	antimicrobial susceptibility testing	MIC	minimum inhibitory concentration
cUTIs	complicated urinary tract infections	MSL	medical science liaison
FDA	US Food and Drug Administration	HABP	hospital-acquired bacterial pneumonia
ID-CAMHB	iron-depleted cation-adjusted Mueller-Hinton broth	SNP	single nucleotide polymorphism
IHMA	International Health Management Associates	VABP	ventilator-associated bacterial pneumonia
MALDI-TOF	matrix-assisted laser desorption/ionization-time of flight mass spectrometry	WGS	whole genome sequencing

References

1. Data on File 113. Shionogi Inc.
2. Fetroja® (cefiderocol) for injection, for intravenous use [Prescribing Information]. Shionogi Inc.