FETROJA – TEMPERATURE EXCURSION PARAMETERS FOR UNRECONSTITUTED POWDER IN VIALS

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 read the attached Fetroja Full Prescribing Information.**

As stated in **Section 16.2 Storage and Handling** of the Fetroja **Full Prescribing Information**:[1]

> Fetroja vials should be stored refrigerated at 2°C to 8°C (36°F to 46°F). Protect from light. Store in the carton until time of use.

Unreconstituted Fetroja powder in vials that are stored outside the recommended temperatures will tolerate:[2]

- Upper temperature: Cumulative 6 days below **30°C (86°F)**
- Lower temperature: Cumulative 15 days above **-20°C (-4°F)**

Time out of refrigeration (TOR) during transportation of the product should also be considered when making a determination on the impact that a temperature excursion may have on Fetroja vials. **Table 1** below provides transportation time of the Fetroja vials out of refrigeration and remaining temperature excursion tolerances for Lot No. 0054. Please note that the information provided is specific to each lot of Fetroja and is intended to assist you in determining total excursion time.

Table 1. Temperature Excursion Data for Fetroja Vial Lot No. 0054[2]

Maximum Excursions Tolerated	Transportation TOR	Remaining TOR Tolerances
6 days below 30°C (86°F)	10 h	5 days 14 h below 30°C (86°F)
15 days above -20°C (-4°F)	None	15 days above -20°C (-4°F)

Abbreviations: h, hours; TOR, time out of refrigeration.

There is no available data regarding the impact of exposure to light on Fetroja powder in the vials.[2]

Please refer to **Section 16.2** of the Fetroja **Full Prescribing Information** for proper storage and handling of Fetroja vials.

RELEVANT PRESCRIBING INFORMATION

Fetroja® is indicated in patients 18 years of age or older for the treatment of:[1]

- Complicated urinary tract infections (cUTIs), including pyelonephritis caused by the following susceptible Gram-negative microorganisms: *Escherichia coli*, *Klebsiella pneumoniae*, *Proteus mirabilis*, *Pseudomonas aeruginosa*, and *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,* and *Serratia marcescens*

Fetroja is contraindicated in:[1]

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

REFERENCES

1. Fetroja® (cefiderocol) for injection, for intravenous use [Prescribing Information]. Shionogi Inc.
2. Data on File 70. Shionogi Inc.

ENCLOSURE

Fetroja® (cefiderocol) for injection, for intravenous use [Prescribing Information]. Shionogi Inc.