WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Fetcroja 1 g powder for concentrate for solution for infusion [1]

Cefiderocol (as sulfate tosylate) 1 g powder for concentrate for solution for infusion

Fetcroja 1 g powder for concentrate for solution for infusion was submitted in 2023 by Shionogi B.V. Amsterdam, The Netherlands. to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for the treatment of multi-drug resistant bacterial infections on 22 February 2024.

Information on the site(s) involved in the manufacture of the product and the API is available at the products listing information: https://extranet.who.int/prequal/medicines/mr001

The "Procedure for prequalification of pharmaceutical products[2]" defines specific evaluation mechanisms for products approved by regulatory authorities, which apply similar stringent standards for quality, safety and efficacy as those required by WHO.

The prequalification of this product by the WHO Prequalification Team: Medicines (PQTm), is based on the approval by the European Medicines Agency (EMA https://www.ema.europa.eu/en/medicines), in line with the "Guidelines on submission of documentation for prequalification of finished pharmaceutical products approved by stringent regulatory authorities" [3].

Hence, no assessment of the data underlying this approval has been undertaken within the WHO Prequalification Programme.

However, according to the SRA guideline WHO may request additional data when considered necessary for the safe use of the product in regions relevant for prequalified products and such information may be included in the WHOPAR as a separate piece of information. In order to safeguard product quality throughout its entire intended shelf-life in hot and very humid areas, stability studies under the conditions defined for Climatic Zones IVb have been requested from the Applicant[4].

Based on the submitted stability data WHO PQTm considers the following storage condition appropriate for the product when distributed in regions with zone III, IVa and IVb climatic conditions, based on available stability information:

[1] Trade names are not prequalified by WHO. This is the National Medicines Regulatory Authority's responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

[2] https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/prequalification/trs961-annex10-who-procedure-prequalification.pdf?sfvrsn=85029f47_2

[3] https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/prequalification/trs986-annex5.pdf?sfvrsn=8aae767d_2

[4] https://extranet.who.int/prequal/sites/default/files/document_files/48%20Stability%20data%20SRA%20FPPs_March2016_newtempl.pdf

- Store in a refrigerator (2°C – 8°C). Store in the original carton in order to protect from light.
- The shelf-life for the powder at this storage condition is 36 months.

- Stability of reconstituted solution in the vial: Chemical and physical in-use stability after reconstitution has been demonstrated for 1 hour at 25°C.

Based on the above, the WHOPAR for Fetcroja refers for parts 1, 3, 4, 5, 6 and 8 to the previously issued public assessment report as follows:

WHOPAR part		**Reference**[5]
Part 1	Summary for the Public	https://www.ema.europa.eu/en/documents/overview/fetcroja-epar-medicine-overview_en.pdf
Part 3	Package Leaflets	https://www.ema.europa.eu/en/documents/product-information/fetcroja-epar-product-information_en.pdf
Part 4	Summaries Product Characteristics	https://www.ema.europa.eu/en/documents/product-information/fetcroja-epar-product-information_en.pdf
Part 5	Labelling	https://www.ema.europa.eu/en/documents/product-information/fetcroja-epar-product-information_en.pdf
Part 6	Discussion	https://www.ema.europa.eu/en/documents/assessment-report/fetcroja-epar-public-assessment-report_en.pdf
Part 8	Steps taken following Authorisation	https://www.ema.europa.eu/en/documents/procedural-steps-after/fetcroja-epar-procedural-steps-taken-and-scientific-information-after-authorisation_en.pdf

Parts 2 and 7 of the WHOPAR for Fetcroja are included here.

Fetcroja 1 g powder for concentrate for solution for infusion contains cefiderocol (as sulfate tosylate)

Its WHO recommended use is for the treatment of multi-drug resistant bacterial infections.

Summary of Prequalification Status for
Fetcroja 1 g powder for concentrate for solution for infusion

Initial acceptance	**Date**	**Outcome**
Status on PQ list	22 February 2024	listed
Quality	February 2024	MR
PQ: prequalification MR: meets requirements		

The table represents the status of relevant completed activities only.

[5] https://www.ema.europa.eu/en/medicines/human/EPAR/fetcroja