

WHO Prequalification Programme WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Rocephin 1 g Powder for solution for injection or infusion¹

Ceftriaxone (as sodium) 1g Powder for solution for injection or infusion

Rocephin 1 g Powder for solution for injection or infusion was submitted in 2017 by Roche Products Limited. to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for the treatment of bacterial infections in HIV/AIDS patients on 22 February 2018.

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/pqweb/medicines/ha692>)

The “Procedure for prequalification of pharmaceutical products²” 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 United Kingdom “Medicines & Healthcare products Regulatory Agency” (<https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency>), 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 Applicant⁴.

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:

- Do not store above 25°C. Keep vial in the outer carton in order to protect from light.
- The shelf-life at this storage condition is 36 months.

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=8aac767d_2

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

This WHOPAR refers to the information available at the approving stringent regulatory authority's website resulting from the assessment of the quality, efficacy and safety as well as steps taken after approval.

<https://www.gov.uk/guidance/find-product-information-about-medicines>

For details on the uses of this product, for relevant efficacy and safety information see the summary of product characteristics and the patient information leaflet as approved by NMRA.

<https://products.mhra.gov.uk/search/?search=PL+00031%2F0171&page=1> PL00031/0171)

This WHOPAR for Rocephin 1 g Powder is comprised of parts 2, 5 and 7.

Rocephin 1 g Powder for solution for injection or infusion contains ceftriaxone (as sodium)
Its WHO recommended use is for treatment of bacterial infections in HIV/AIDS patients.

**Summary of Prequalification Status for
Rocephin 1 g Powder for solution for injection or infusion**

Initial acceptance	Date	Outcome
Status on PQ list	22 February 2018	listed
Quality	February 2018	MR
PQ: prequalification MR: meets requirements		

The table represents the status of relevant completed activities only.