WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Meropenem 1 g Powder for Solution for Injection or Infusion[1]

International Nonproprietary Name (INN):
Meropenem

Abstract

Meropenem 1 g Powder for Solution for Injection or Infusion, manufactured at Venus Remedies Limited Bhatoli Kalan, Baddi, Distt. Solan (Himachal Pradesh) India and Venus Pharma GmbH, Am Bahnhof 1-3, 59368 Werne, Germany was submitted to be considered for prequalification in 2020 when the product was licensed / registered in the United Kingdom and subsequently accepted for the WHO list of prequalified products for the treatment of tuberculosis on 03 March 2020.

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 a stringent regulatory authority (SRA), namley the United Kingdom Medicines and Healthcare products Regulatory Agency" MHRA (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, stability studies under the conditions defined for Climatic Zones IVb have been requested from the Applicant.

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.
The shelf-life at this storage condition is 24 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] http://www.who.int/medicines/areas/quality_safety/quality_assurance/TRS961_Annex10.pdf
[3] https://extranet.who.int/prequal/key-resources/documents/clarification-respect-stringent-regulatory-organization-applicable-stringent
http://apps.who.int/prequal/info_general/documents/TRS986/TRS986_ANNEX-5_SRA-Guide.pdf

https://extranet.who.int/prequal/sites/default/files/documents/75%20SRA%20clarification_February2017_0.pdf

This WHOPAR refers to the information available at the approving stringent regulatory authority in terms of the assessment of the quality, efficacy and safety as well as steps taken after the prequalification (https://products.mhra.gov.uk/?search=PL%2034985%2F0004&page=1&doc=
PL 34985/0004 last assessed May 2020)
Parts 2 and 7 of the WHOPAR for Meropenem 1 g Powder for Solution for Injection or Infusion are included here.

Meropenem 1 g Powder for Solution for Injection or Infusion contains meropenem trihydrate. Its WHO recommended use is for the treatment of tuberculosis.

The most frequent adverse reactions observed during treatment with meropenem were diarrhoea, nausea/vomiting, headache, rash, and increased hepatic enzymes.
The most serious adverse effects of meropenem are thrombocythaemia fatal hypersensitivity reactions, antibiotic-associated colitis and pseudomembranous colitis and paraesthesiae.

The efficacy and safety profile of meropenem is well established based on the extensive clinical experience in the treatment and the management of tuberculosis.

Summary of Prequalification Status for
Meropenem 1 g Powder for Solution for Injection or Infusion

Initial acceptance	**Date**	**Outcome**
Status on PQ list	03 March 2020	listed
Quality	29 November 2019	MR

MR: meets requirements

The table represents the status of relevant completed activities only.