WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

PETEHA, 250 mg, Filmtabletten[1]

Protionamide 250 mg film-coated tablets

PETEHA 250 mg, film-coated tablets was submitted in 2017 by RIEMSER Pharma GmbH, to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for the treatment of tuberculosis on 14 March 2018. The name of the applicant changed to Esteve Pharmaceuticals GmbH in July 2022

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/tb345

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 German "Federal Institute for Drugs and Medical Devices" (https://www.bfarm.de/EN/Home/home_node.html) 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

- **PVC-Aluminium blister cards:**

  Do not store above 25°C.
  The shelf-life at this storage condition is 60 months.

- **Plastic containers (securitainers):**

  Do not store above 30°C.
  The shelf-life at this storage condition is 60 months.

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.pharmnet-bund.de/static/de/index.html Registration nr 6192821.00.00)

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.

The English language version of the patient information leaflet, the summary of product characteristics and the labelling, as certified to be "BfArM" approved texts, are included in this WHOPAR.

This WHOPAR for PETEHA is comprised of parts 2, 3. 4. 5 and 7.

PETEHA contains protionamide. Its WHO recommended use is for the treatment of tuberculosis.

Summary of Prequalification Status for PETEHA, 250 mg, film-coated tablets

	Initial Acceptance		**Requalification**	
	Date	**Outcome**	**Date**	**Outcome**
Status on PQ list	14 March 2018	listed	16 September 2025	listed
Dossier Evaluation	March 2018	MR	September 2025	requalified
PQ: prequalification MR: meets requirements				

The table represents the status of relevant completed activities only.