WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Pretomanid Tablets 200 mg [1]

Pretomanid tablets 200 mg

Pretomanid Tablets 200 mg was submitted in 2020 by Mylan Laboratories Limited. to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for the treatment of drug-resistant tuberculosis on 25 November 2020.

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/tb386

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 the U.S.Food and Drug Administration "USFDA" (https://www.fda.gov/),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].

[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

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 30°C.

- The shelf-life at this storage condition is:
  - 48 months for the bottle packs containing 26 tablets each
  - 24 months for bottle packs containing 182 tablets each
  - 48 months for the blister packs

This WHOPAR refers to the information available at the approving (https://www.fda.gov/drugs) stringent regulatory authority's website resulting from the assessment of the quality, efficacy and safety as well as steps taken after approval.

For details on the uses of this product, for relevant efficacy and safety information, see the Prescribing Information as approved by USFDA: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.process (New Drug Application (NDA): 212862)

This WHOPAR for Pretomanid Tablets is comprised of parts 2, 5 and 7.

Pretomanid Tablets 200 mg contains pretomanid. Its WHO recommended use is in combination with other tuberculosis medicines for the treatment of durg-resistent tuberculosis due to *Mycobacterium tuberculosis* in adults and adolescents at least 14 years old.

Summary of Prequalification Status for Pretomanid Tablets 200 mg

	Initial Acceptance	
	Date	**Outcome**
Status on PQ list	25 November 2020	listed
Dossier Evaluation	November 2020	MR
PQ: prequalification MR: meets requirements		

The table represents the status of relevant completed activities only.