WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Pretomanid Tablets 200 mg[1]

Pretomanid tablets 200 mg

Abstract

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 MDR/XDR 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/pqweb/medicine/4296)

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), 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].

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: 24 months for the bottle packs and 18 months for the blister packs.

[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/pqweb/sites/default/files/documents/48%20Stability%20data%20SRA%20FPPs_March2016_newtempl.pdf

This WHOPAR refers to the information available at the approving (https://www.fda.gov/) 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 and for side effects and warnings, 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)

Parts 2, 5 and 7 of the WHOPAR for Pretomanid Tablets 200 mg are included here.

Pretomanid Tablets 200 mg contains pretomanid. Its WHO recommended use is:
"Pretomanid in combination with bedaquiline and linezolid (BPaL) may be used under operational research conditions in multidrug-resistant tuberculosis (MDR-TB) patients with TB that is resistant to fluoroquinolones, who have either had no previous exposure to bedaquiline and linezolid or have been exposed for no more than 2 weeks."

The efficacy and safety profile of pretomanid is based on limited clinical safety and efficacy data. This product is indicated for use in a limited and specific population of patients.

Summary of Prequalification Status for Pretomanid Tablets 200 mg:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	25 November 2020	listed
Quality	November 2020	MR
PQ: prequalification MR: meets requirements		

The table represents the status of relevant completed activities only.