WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Ivermectin Tablets USP [1]

Ivermectin 3mg Tablets

Ivermectin Tablets USP, manufactured at Ingenus Pharmaceuticals NJ, LLC (formerly known as Mirror Pharmaceuticals, LLC), Fairfield, N.J. 07004, USA, was submitted to be considered for prequalification in 2020 and subsequently accepted for the WHO list of prequalified products for treatment of soil-transmitted helminthiasis, strongyloidiasis, onchocerciasis, lymphatic filariasis and scabies on 16 September 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), the U.S.Food &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 25°C.

The shelf-life at this storage condition is 24 months.

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[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=overview.process&ApplNo=204154 Abbreviated New Drug Application (ANDA): 204154)

Parts 2, 5, and 7 of the WHOPAR for Ivermectin Tablets USP are included here.

Ivermectin Tablets USP contains ivermectin. Its WHO recommended uses are

- for the treatment and elimination of onchocerciasis
- together with albendazole for control of microfilaraemia and elimination of lymphatic filariasis in countries in which onchocerciasis is also present. Where onchocerciasis and loaiasis are not endemic, Ivermectin Tablets USP may be used with albendazole and diethylcarbamazine. Treatment is given to the entire eligible population via a mass drug administration programme in endemic areas
- for the treatment of intestinal (non-disseminated) strongyloidiasis
- with albendazole, including as part of mass drug administration programmes for the treatment of other soil-transmitted intestinal worm infections.
- for the treatment of severe or crusted scabies. It is also indicated for mild or moderate scabies when topical treatments are ineffective or cannot be used.

The efficacy and safety profile ivermectin is well established based on the extensive clinical experience in the treatment of neglected tropical diseases.

Summary of Prequalification Status for Ivermectin Tablets USP

Initial acceptance	**Date**	**Outcome**
Status on PQ list	16 September 2020	listed
Quality	September 2020	MR

MR: meets requirements

The table represents the status of relevant completed activities only.