WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

PETEHA® 250 mg, film-coated tablets[1]

International Nonproprietary Name (INN):
Protionamide 250 mg tablets

Abstract

PETEHA® 250 mg, film-coated tablets, manufactured at SW Pharma GmbH, Schiffweiler, Germany, was submitted to be considered for prequalification in 2017 when the product was licensed / registered in Germany and subsequently accepted for the WHO list of prequalified products for the treatment of tuberculosis on 14 March 2018.

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 of Medicines Programme (PQP) is based on the approval by a stringent regulatory authority (SRA), namely 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, stability studies under the conditions defined for Climatic Zones IVb have been requested from the Applicant.

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:

Blister packs:
Do not store above 25°C.
The shelf-life at this storage condition is 60 months.
Bottle packs:
Do not store above 30°C.
The shelf-life at this storage condition is 60 months.

[1] Trade names are not prequalified by WHO. This is the National Medicines Regulatory Authority's (NMRA) 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] 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

The English language version of the Patient Information Leaflet, the Summary of Product Characteristics and the labelling, which is a company authorized English translation of the approved German texts, are included in this WHOPAR.

Parts 2a, 2b, 3, 4, 5 and 7 of the WHOPAR for PETEHA® 250 mg, film-coated tablets are included here.

PETEHA® 250 mg, film-coated tablets contains protionamide. Its WHO recommended use is for the treatment of tuberculosis.
The most frequent adverse reactions observed during treatment with protionamide are epigastric discomfort, abdominal pain, anorexia, nausea, vomiting diarrhoea and elevated serum transaminases.
The most serious adverse reactions of protionamide are hepatitis, psychotic disturbances, encephalopathy, peripheral and optic neuritis and pellagra like syndrome.

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

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

	Initial Acceptance	
	Date	**Outcome**
Status on PQ list,	14 March 2018	listed
Dossier Evaluation	07 March 2018	MR

MR: meets requirements

The table represents the status of relevant completed activities only.