WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Praziquantel Tablets 600mg[1]

International Nonproprietary Name(s) (INN)/strength/pharmaceutical form
Praziquantel 600mg Tablets

Abstract

Praziquantel Tablets 600mg, manufactured at Macleods Pharmaceuticals Limited, Himachal Pradesh, India was included in the WHO list of prequalified medicinal products for large scale preventive chemotherapy interventions for the control of schistosoma infections on 5 September 2017.

Praziquantel Tablets 600mg is indicated for large scale preventive chemotherapy interventions for the control of schistosoma infections due to various types of blood fluke worms following the recommendations of the WHO Global Programme to Eliminate Schistosomiasis.
Detailed information on the use of this product is described in the Summary of Product Characteristics (SmPC), which can be found in this WHOPAR.

The active pharmaceutical ingredient (API) of Praziquantel Tablets 600mg is praziquantel.

The most frequent adverse events observed during treatment with praziquantel were headache, dizziness, fatigue, abdominal pain, nausea, vomiting, and urticaria.

The most important safety concerns with praziquantel are generalised hypersensitivity, arrhythmia, eosinophilia, pruritis and fatigue

The efficacy and safety profile of praziquantel is well established based on extensive clinical experience in the treatment of schistosoma infections.

On the basis of data submitted and public information on the use of praziquantel in schistosoma infections, the team of assessors advised that Praziquantel Tablets 600mg is of acceptable quality, efficacy and safety to allow inclusion of Praziquantel Tablets 600mg in the list of prequalified medicinal products.

[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.

Summary of Prequalification Status for Praziquantel Tablets 600mg:

	Initial Acceptance					
	Date	**Outcome**	**Date**	**Outcome**	**Date**	**Outcome**
Status on PQ list, i.e. date of listing	05 Sept 2017					
Dossier Evaluation (Quality assurance)						
Quality	14 Aug 2017	MR				
Bioequivalence	22 Aug 2017	MR				
Inspection Status						
GMP(re-)inspection						
API	NA	NA				
FPP	17 July 2014	MR				
GCP/GLP (re-)inspection	14 July 2017	MR				

MR: Meets Requirements
NA: not applicable, not available