WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[NT008 trade name]*

Praziquantel 600 mg Tablets

[NT008 trade name], manufactured at Medopharm Private Limited, Guduvanchery, Tamilnadu, India, was included in the WHO list of prequalified medicinal products for the treatment of neglected tropical diseases on 22 April 2021.

[NT008 trade name] is indicated for elimination of schistosoma infections through mass drug administration programmes. 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 of [NT008 trade name] is praziquantel.

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

For details on the uses of this product and for side effects and warnings, see Part 4 of this WHOPAR (summary of product characteristics).

On the basis of data submitted and public information on the use of praziquantel in neglected tropical diseases, the team of assessors advised that [NT008 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [NT008 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [NT008 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	22 April 2021	listed
Quality	05 March 2021	MR
Bioequivalence	11 March 2021	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	15 February 2018	MR
FPP	03 July 2020	MR*
GCP/GLP (re-)inspection	22 November 2019	MR
API: active pharmaceutical ingredient FPP: finished pharmaceutical product GCP: good clinical practice [quality standard] GLP: good laboratory practice [quality standard]	GMP: good manufacturing practice [quality standard] MR: meets requirements MR*: desk review (based on recent inspection reports) NA: not applicable, not available PQ: prequalification	

The table represents the status of relevant completed activities only.

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.