

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[NT013 trade name]*

Praziquantel 600 mg tablets

[NT013 trade name], manufactured at Merck S. A. de C.V., Naucalpan de Juárez, Mexico, was included in the WHO list of prequalified medicinal products for the treatment of neglected tropical diseases on 22 February 2024.

[NT013 trade name] is indicated for use for the following parasitic infections: schistosomiasis, taeniasis, neurocysticercosis and foodborne trematodiasis. 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 [NT013 trade name] is praziquantel.

The efficacy and safety of praziquantel is well established based on extensive clinical experience in the treatment of parasitic 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 [NT013 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [NT013 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [NT013 trade name]:

The table shows the status of relevant completed activities, including the dates of WHO internal quality assurance.

Initial acceptance	Date	Outcome
Status on PQ list	22 February 2024	listed
Pharmaceutical quality	09 February 2024	MR
Bioequivalence	12 February 2024	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	01 February 2021	MR*
FPP	18 July 2022	MR*
GCP/GLP (re-)inspection	16 September 2022	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	

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