

WHO Prequalification Programme

WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB309 trade name]*

Isoniazid/pyrazinamide/rifampicin 50 mg/150 mg/75 mg dispersible tablets

[TB309 trade name], manufactured at Macleods Pharmaceuticals Limited, Kachigam, Daman, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 12 December 2017.

[TB309 trade name] is indicated in children weighing less than 25 kg, for the initial treatment of non-severe tuberculosis (TB) due to drug-susceptible *Mycobacterium tuberculosis*. It is also indicated in combination with other medicine(s), in infants and children weighing less than 25 kg, for the initial treatment of drug-susceptible *M. tuberculosis* tuberculosis that does not meet the criteria for non-severe TB. 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 ingredients of [TB309 trade name] are isoniazid, pyrazinamide and rifampicin.

The efficacy and safety of isoniazid, pyrazinamide and rifampicin are well established based on extensive clinical experience in the treatment of tuberculosis.

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 isoniazid, pyrazinamide and rifampicin in tuberculosis, the team of assessors advised that [TB309 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB309 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB309 trade name]:

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

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

Initial acceptance	Date	Outcome
Status on PQ list	12 December 2017	listed
Pharmaceutical quality	29 November 2017	MR
Bioequivalence	05 December 2017	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	22 July 2015	MR
API	13 Nov 2015	MR
API	16 Sept 2016	MR
API	24 Aug 2017	MR
API	26 Aug 2017	MR
APIs	28 Aug 2017	MR
FPP	NA	NA
GCP/GLP (re-)inspection	14 July 2017	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		