WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA762 trade name][*]

Isoniazid/Pyridoxine hydrochloride/ Sulfamethoxazole/Trimethoprim 300mg/25mg/800mg/160mg tablets

[HA762 trade name], manufactured at Mylan Laboratories Limited, Dhar, Madhya Pradesh, India, was included in the WHO list of prequalified medicinal products on 11 July 2022, for the prevention of certain opportunistic infections in people living with HIV.

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 [HA762 trade name] are isoniazid, pyridoxine hydrochloride, sulfamethoxazole and trimethoprim.

The efficacy and safety of are isoniazid, pyridoxine hydrochloride, sulfamethoxazole and trimethoprim are well established based on extensive clinical experience in the prevention of certain opportunistic 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 isoniazid, pyridoxine hydrochloride, sulfamethoxazole and trimethoprim in HIV, the team of assessors advised that [HA762 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA762 trade name] in the list of prequalified medicinal products.

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

Summary of prequalification status for [HA762 trade name]:

Initial acceptance	Date	Outcome
Status on PQ list	11 July 2022	listed
Quality	24 June 2022	MR
Bioequivalence	29 June 2022	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	22 February 2019	MR
API	26 July 2019	MR*
API	22 October 2019	MR*
API	21 September 2020	MR*
FPP	08 July 2021	MR*
GCP/GLP (re-)inspection	11 March 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

The table represents the status of relevant completed activities only.