WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA735 trade name]*

Sulfamethoxazole/trimethoprim 400 mg/80 mg tablets

[HA735 trade name], manufactured at Macleods Pharmaceuticals Limited, Tehsil Baddi, Himachal Pradesh, India, was included in the WHO list of prequalified medicinal products for the treatment and prevention of infections in human immunodeficiency virus (HIV)/AIDS patients on 28 January 2021.

[HA735 trade name] is indicated for the treatment and prophylaxis of opportunistic infections in patients with HIV-1 weighing at least 8 kg. 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 [HA735 trade name] are sulfamethoxazole and trimethoprim.

The efficacy and safety of sulfamethoxazole and trimethoprim are well established based on extensive clinical experience in the treatment prophylaxis of opportunistic infections in patients with HIV-1.

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 sulfamethoxazole/trimethoprim 400 mg/80 mg tablets in HIV infections, the team of assessors advised that [HA735 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA735 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 [HA735 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	28 January 2021	listed
Quality	20 January 2021	MR
Bioequivalence	26 January 2021	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	22 February 2019	MR
API	25 January 2021	MR*
FPP	23 October 2019	MR
GCP/GLP (re-)inspection	1 September 2020	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.