

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA686 trade name]*

Sulfamethoxazole/Trimethoprim 400 mg/80 mg tablets

[HA686 trade name], manufactured at Mylan Laboratories Limited, Pithampur, Madhya 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 05 April 2019.

[HA686 trade name] is indicated for treatment and prevention of infections susceptible to sulfamethoxazole and trimethoprim in patients with HIV infection. 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 [HA686 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 of and prevention of infections in HIV/AIDS patients.

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 and trimethoprim in HIV/AIDS, the team of assessors advised that [HA686 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA686 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA686 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	05 April 2019	listed
Pharmaceutical quality	19 March 2019	MR
Bioequivalence	21 March 2019	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
APIs	NA	NA
FPP	25 May 2019	MR
GCP/GLP (re-)inspection	29 March 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	

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