

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA774 trade name]*

Sulfamethoxazole/trimethoprim 400 mg/80 mg tablets

[HA774 trade name], manufactured at Shouguang Fukang Pharmaceutical Company Limited, Shouguang, China, was included in the WHO list of prequalified medicinal products for the prevention and treatment of infections in HIV/AIDS on 18 December 2023.

[HA774 trade name] is indicated for prevention and treatment of infections in infants, children and adults 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 [HA774 trade name] are sulfamethoxazole and trimethoprim.

The efficacy and safety of sulfamethoxazole and trimethoprim are well established based on extensive clinical experience in the prevention and treatment of infections in HIV 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 [HA774 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA774 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA774 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	18 December 2023	listed
Pharmaceutical quality	27 November 2023	MR
Bioequivalence	06 December 2023	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	NA	NA
FPP	11 December 2023	MR*
GCP/GLP (re-)inspection	NA	NA
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.