WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA744 trade name]*

Sulfamethoxazole-trimethoprim 400 mg/80 mg tablets

[HA744 trade name], manufactured at Ipca Laboratories Limited, Silvassa, U.T. of Dadra and Nagar Haveli and Daman and Diu, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS related conditions on 17 February 2021.

[HA744 trade name] is indicated for the prevention of *Pneumocystis jirovecii* pneumonia, toxoplasmosis, malaria and some severe bacterial infections in adults and children with HIV, including pregnant women and children younger than 5 years. [HA744 trade name] is also indicated for the treatment of HIV-related *Pneumocystis jirovecii* pneumonia and toxoplasmosis. 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 [HA744 trade name] are a fixed dose combination of sulfamethoxazole and trimethoprim.

The efficacy and safety of sulfamethoxazole and trimethoprim are well established based on extensive clinical experience in the treatment of HIV/AIDS-related 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 sulfamethoxazole-trimethoprim in HIV/AIDS-related infections, the team of assessors advised that [HA744 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA744 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA744 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	17 February 2021	listed
Quality	02 February 2021	MR
Bioequivalence	06 February 2021	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	22 February 2019	MR
API	31 May 2018	MR
FPP	25 January 2021	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