WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA691 trade name][*]
Sulfamethoxazole/Trimethoprim 800 mg/160 mg Tablets

Abstract

[HA691 trade name] manufactured at Milan Laboratories (India) Pvt Ltd, Maharashtra, 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 17 December 2019.

[HA691 trade name] is indicated for treatment and prevention of infections susceptible to sulfamethoxazole and trimethoprim in patients with HIV infection. Such infections include *Pneumocystis jiroveci* pneumonitis, toxoplasmosis encephalitis, *Plasmodium falciparum* malaria, norcardiosis, brucellosis and certain bacterial infections.

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 (APIs) of [HA691 trade name] are the antibacterial agents, sulfamethoxazole and trimethoprim. The APIs are well-established and documented for the treatment and prevention of infections in Human Immunodeficiency Virus (HIV)/AIDS patients.

The efficacy and safety profiles of sulfamethoxazole and trimethoprim are well established based on extensive clinical experience in the treatment and prevention of infections in HIV patients.

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 [HA691 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA691 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 [HA691 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	17 December 2019	Listed
Quality	12 December 2019	MR
Bioequivalence	15 December 2019	MR
Safety, Efficacy	NA	NA
GMP(re-)inspection		
API	19 February 2019	MR
API	24 May 2019	MR
FPP	04 February 2019	MR
GCP/GLP (re-)inspection	27 July 2018	MR

MR: meets requirements
NA: not applicable, not available