WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Isoniazid/Pyridoxine hydrochloride/Sulfamethoxazole/Trimethoprim
300 mg/25 mg/800 mg/160 mg Tablets[1]

Abstract

Isoniazid/Pyridoxine hydrochloride/Sulfamethoxazole/Trimethoprim 300 mg/25 mg/800 mg/160 mg Tablets manufactured by Cipla Limited, Patalganga, District - Raigad, Maharashtra, Pin code: 410 220, India was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 21 December 2016.

Isoniazid/Pyridoxine hydrochloride/Sulfamethoxazole/Trimethoprim 300 mg/25 mg/800 mg/160 mg Tablets is indicated for HIV-infected adults, adolescents and children for the prevention of opportunistic infections particularly tuberculosis, *Pneumocystis jiroveci* (*P. carinii*) pneumonia, *Plasmodium falciparum* malaria, toxoplasmosis and bacterial infections sensitive to sulfamethoxazole/trimethoprim.

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 ingredient (API) of Isoniazid/Pyridoxine hydrochloride/Sulfamethoxazole/ Trimethoprim 300 mg/25 mg/800 mg/160 mg Tablets are the antimicrobial agents isoniazid, sulfamethoxazole and trimethoprim, and the vitamin substance pyridoxine hydrochloride. The APIs are documented for the treatment and prevention of tuberculosis, malaria and other microbial infections.

The most frequent adverse events observed during treatment with Isoniazid, Pyridoxine hydrochloride, Sulfamethoxazole and Trimethoprim were diarrhoea, headache, nausea, candida overgrowth and rash.

The most serious safety concerns with Isoniazid/Pyridoxine hydrochloride/Sulfamethoxazole/ Trimethoprim 300 mg/25 mg/800 mg/160 mg Tablets is serious skin reactions (such as Stevens-Johnson syndrome and toxic epidermal necrolysis), liver disorders and myelosuppression (including anaemia, leucopenia, pancytopenia and thrombocytopenia), sideroblastic anaemia, aseptic meningitis, hypersensitivity reactions including pulmonary hypersensitivity reactions, antibiotic-associated diarrhoea and colitis, and hypoglycaemia.

The efficacy and safety profile of Isoniazid/Pyridoxine hydrochloride/Sulfamethoxazole/Trimethoprim 300 mg/25 mg/800 mg/160 mg Tablets is well established based on extensive clinical experience in the treatment and prevention of bacterial and other microbial infections.

On the basis of data submitted and public information on the use of Isoniazid/Pyridoxine hydrochloride/ Sulfamethoxazole/Trimethoprim 300 mg/25 mg/800 mg/160 mg Tablets in the prevention of opportunistic infections in HIV patients, the team of assessors advised that Isoniazid/Pyridoxine hydrochloride/Sulfamethoxazole/Trimethoprim 300 mg/25 mg/800 mg/160 mg Tablets is of acceptable quality, efficacy and safety to allow inclusion of Isoniazid/Pyridoxine hydrochloride/ Sulfamethoxazole/Trimethoprim 300 mg/25 mg/800 mg/160 mg Tablets in the list of prequalified medicinal products.

[1] Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

Summary of Prequalification Status for Isoniazid/Pyridoxine hydrochloride/Sulfamethoxazole/ Trimethoprim 300 mg/25 mg/800 mg/160 mg Tablets:

	Initial Acceptance					
	Date	**Outcome**	**Date**	**Outcome**	**Date**	**Outcome**
Status on PQ list, i.e. date of listing	21 Dec 2016	listed				
Dossier Evaluation (Quality Assurance)						
Quality	16 Nov 2016	MR				
Bioequivalence	30 Mar 2015	MR				
Safety, Efficacy	NA	NA				
Inspection Status						
GMP(re-)inspection						
API	21 Oct 2015	MR				
FPP	18 June 2015	MR				
GCP (re-)inspection	NA	NA				

MR: meets requirements
NA: not applicable, not available