WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Oflox 400 Tablets*

International Nonproprietary Name(s) (INN)/strength/pharmaceutical form:
Ofloxacin 400 mg film-coated tablets

Abstract

Oflox 400 Tablets, manufactured at Cipla Ltd, Patalganga Industrial Area, Raigad District, Maharashtra, India was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 22 December 2011.

Oflox 400 Tablets is indicated for the treatment of tuberculosis. 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 Oflox 400 Tablets is the antibacterial agent ofloxacin. The API is documented for the treatment of tuberculosis and other bacterial infections.

The most frequent adverse events observed during treatment with ofloxacin were diarrhoea, nausea and increases of hepatic enzymes.

The most serious safety concerns with ofloxacin are prolongation of QT interval, fulminant hepatitis potentially leading to liver failure (including fatal cases), bullous skin reactions like Stevens-Johnson syndrome or toxic epidermal necrolysis, psychiatric reactions rarely progressing to suicidal thoughts or attempts, seizures, pseudomembranous colitis, tendon rupture and inflammation, and agranulocytosis.

The efficacy and safety profile of Oflox 400 Tablets is established based on extensive clinical experience in the treatment of bacterial infections.

On the basis of data submitted and public information on the use of ofloxacin in antituberculosis therapy, the team of assessors advised that Oflox 400 Tablets is of acceptable quality, efficacy and safety to allow inclusion of Oflox 400 Tablets in the list of prequalified medicinal products.

* Trade names are not prequalified by WHO. This is under local drug regulatory authority's responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

Summary of Prequalification Status for Oflox 400 Tablets:

	Initial Acceptance					
	Date	**Outcome**	**Date**	**Outcome**	**Date**	**Outcome**
Status on PQ list	22 Dec 2011	listed				
Dossier Evaluation (Quality assurance)						
Quality	16 Dec 2011	MR				
Bioequivalence	16 Dec 2011	MR				
Safety, Efficacy	NA	NA				
Inspection Status						
GMP(re-)inspection						
API	14 Nov 2011	MR				
FPP	24 Feb 2011	MR				
GCP (re-)inspection	NA	NA				
Batch Analysis	NA	NA				

MR: meets requirements
NA: not applicable, not available