WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Levofloxacin 250 mgTablets*

International Nonproprietary Name(s) (INN):
levofloxacin

Abstract

Levofloxacin 250 mg Tablets, manufactured at Micro Labs Ltd, Tamilnadu, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 3 October 2012.

Levofloxacin 250 mg 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 Levofloxacin 250 mg Tablets is the antibacterial agent levofloxacin. The API is documented for the treatment of tuberculosis and other bacterial infections.

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

The most serious safety concerns with levofloxacin 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 levofloxacin 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 levofloxacin in antituberculosis therapy, the team of assessors advised that Levofloxacin 250 mg Tablets is of acceptable quality, efficacy and safety to allow inclusion of Levofloxacin 250 mg Tablets in the list of prequalified medicinal products.

* 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 Levofloxacin 250 mg Tablets:

	Initial Acceptance					
	Date	**Outcome**	**Date**	**Outcome**	**Date**	**Outcome**
Status on PQ list, i.e. date of listing	03 Oct 2012	listed				
Dossier Evaluation (Quality assurance)						
Quality	28 Sept 2012	MR				
Bioequivalence	10 Aug 2012	MR				
Safety, Efficacy	NA	NA				
Inspection Status						
GMP(re-)inspection						
API	22 March 2012	MR				
FPP	20 April 2012	MR				
GCP/GLP (re-)inspection	20 April 2012	MR				
Batch Analysis	NA	NA				

MR: meets requirements
NA: not applicable, not available