WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Emtricitabine/Tenofovir Disoproxil Fumarate 200 mg/300 mg Tablets*

International Nonproprietary Names (INN):
emtricitabine/tenofovir disoproxil fumarate

Abstract

Emtricitabine/Tenofovir Disoproxil Fumarate 200 mg/300 mg Tablets, manufactured at Micro Labs Limited, Verna, Goa, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 27 May 2016.

Emtricitabine/Tenofovir Disoproxil Fumarate 200 mg/300 mg Tablets is indicated in combination with other antiretroviral products for the treatment of human immunodeficiency virus-1 (HIV-1) infection in adults and adolescents from 10 years of age and weighing at least 30 kg. Emtricitabine/Tenofovir Disoproxil Fumarate 200 mg/300 mg Tablets may be used for pre-exposure prophylaxis in adults and adolescents (weighing at least 35 kg) at substantial risk of HIV infection. Consideration should be given to official guidelines for prevention and treatment of HIV-1 infection (e.g. those of the WHO). 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 Emtricitabine/Tenofovir Disoproxil Fumarate 200 mg/300 mg Tablets are the nucleoside reverse transcriptase inhibitor emtricitabine and the nucleotide reverse transcriptase inhibitor tenofovir disoproxil fumarate.

The APIs emtricitabine and tenofovir disoproxil fumarate have been investigated in antiretroviral combination therapy in several clinical trials, in both treatment-naïve and treatment-experienced patients.

The most frequent adverse events observed during treatment with emtricitabine and tenofovir disoproxil fumarate were hypophosphataemia, dizziness, headache, diarrhoea, vomiting, nausea, rash, elevated creatine kinase and asthenia. In addition anaemia was common and skin discolouration (increased pigmentation) was very common when emtricitabine was administered to paediatric patients.

The most serious safety concerns with emtricitabine and tenofovir disoproxil fumarate are renal impairment, renal failure, proximal renal tubulopathy and decreases in bone mineral density. Discontinuation of therapy with Emtricitabine/Tenofovir Disoproxil Fumarate 200 mg/300 mg Tablets in patients co-infected with HIV and HBV may be associated with severe acute exacerbations of hepatitis.

The efficacy and safety profile of emtricitabine and tenofovir disoproxil fumarate is well established based on extensive clinical experience in the treatment of HIV/AIDS.

On the basis of data submitted and public information on the use of emtricitabine and tenofovir disoproxil fumarate in HIV/AIDS, the team of assessors advised that Emtricitabine/Tenofovir

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

Disoproxil Fumarate 200 mg/300 mg Tablets is of acceptable quality, efficacy and safety to allow inclusion of Emtricitabine/Tenofovir Disoproxil Fumarate 200 mg/300 mg Tablets in the list of prequalified medicinal products.

Summary of Prequalification Status for Emtricitabine/Tenofovir Disoproxil Fumarate 200 mg/300 mg Tablets:

	Initial Acceptance					
	Date	**Outcome**	**Date**	**Outcome**	**Date**	**Outcome**
Status on PQ list, i.e. date of listing	27 May 2016	listed				
Dossier Evaluation (Quality assurance)						
Quality	18 March 2016	MR				
Bioequivalence	04 April 2016	MR				
Safety, Efficacy	NA	NA				
Inspection Status						
GMP(re-)inspection						
API	07 March 2014	MR				
API	18 Sept 2014	MR				
API	17 April 2015	MR				
API	04 Dec 2015	MR				
FPP	17 Oct 2014	MR				
GCP (re-)inspection	18 March 2016	MR				

MR: meets requirements
NA: not applicable, not available