WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Dolutegravir 50mg Tablets [1]

International Nonproprietary Name (INN):
Dolutegravir

Abstract

Dolutegravir 50mg Tablets manufactured at Cipla Limited, Pithampur, Madhya Pradesh, India, was included in the WHO list of prequalified medicinal products for the treatment of human immunodeficiency virus (HIV) infection on 24 October 2017.

Dolutegravir 50mg Tablets is indicated in combination with other antiretroviral medicines for the treatment of human immunodeficiency virus (HIV) infected adults and adolescents weighing at least 40kg. 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 Dolutegravir 50mg Tablets is the antiviral agent dolutegravir. The API is well-established and documented for the treatment of human immunodeficiency virus (HIV) infection.

The most frequent adverse events observed during treatment with dolutegravir were nausea, diarrhoea and headache.

The most serious safety concerns of dolutegravir are hypersensitivity reactions that include rash and severe liver effects.

The efficacy and safety profile of Dolutegravir 50mg Tablets is well established based on extensive clinical experience in the treatment of human immunodeficiency virus (HIV) infection.

On the basis of data submitted and public information on the use of dolutegravir therapy in human immunodeficiency virus (HIV) infection the team of assessors advised that Dolutegravir 50mg Tablets is of acceptable quality, efficacy and safety to allow inclusion of Dolutegravir 50mg 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 Dolutegravir 50mg Tablets:

	Initial Acceptance					
	Date	**Outcome**	**Date**	**Outcome**	**Date**	**Outcome**
Status on PQ list, i.e. date of listing	24 Oct 2017	listed				
Dossier Evaluation (Quality assurance)						
Quality	03 Oct 2017	MR				
Bioequivalence	04 Oct 2017	MR				
Inspection Status						
GMP(re-)inspection						
API	15 March 2016	MR				
FPP	06 Oct 2017	MR				
GCP (re-)inspection	23 June 2008	MR				

MR: meets requirements
NA: not applicable, not available