WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

达力嗪 R(DALIQIN)[1]

International Nonproprietary Name (INN)
Ceftriaxone (as sodium)

Abstract

达力嗪 R(DALIQIN) manufactured at Sinopharm Zhijun (Shenzhen) Pharmaceutical Co., Ltd., China was included in the WHO list of prequalified medicinal products for the treatment of bacterial infections in Human Immunodeficiency Virus (HIV)/AIDS patients on 15 August 2016.

达力嗪 R(DALIQIN) is indicated for the treatment of bacterial infections. 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 达力嗪 R(DALIQIN) is the antibacterial agent ceftriaxone. The API is well-established and documented for the treatment of bacterial infections.

The most frequent adverse events observed during treatment with ceftriaxone were eosinophilia, leucopenia, thrombocytopenia, diarrhoea, rash, and hepatic enzymes increased.

The most serious safety concerns with ceftriaxone are renal and hepatic dysfunction.

The efficacy and safety profile of Ceftriaxone is well 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 ceftriaxone in bacterial infections, the team of assessors advised that 达力嗪 R(DALIQIN) of acceptable quality, efficacy and safety to allow inclusion of 达力 R(DALIQIN) in the list of prequalified medicinal products.

[*]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.

Summary of Prequalification Status for 达力嗪 [R] (DALIQIN):

	Initial Acceptance					
	Date	**Outcome**	**Date**	**Outcome**	**Date**	**Outcome**
Status on PQ list, i.e. date of listing	15 Aug 2016					
Dossier Evaluation (Quality assurance)						
Quality	05 July 2016	MR				
Bioequivalence	13 May 2016	MR				
Safety, Efficacy	NA	MR				
Inspection Status						
GMP(re-)inspection						
API	NA	MR				
FPP	16 Oct 2015	MR				
GCP/GLP (re-)inspection	NA	MR				

MR: meets requirements
NA: not applicable, not available