WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Artesun® 120mg [*]

International Nonproprietary Name(s) (INN):
Artesunate 120mg powder for injection s

Abstract

Artesun® 120mg manufactured at Guilin Pharmaceutical Co., Ltd., Guangxi, China, was accepted for the WHO list of prequalified medicinal products for the treatment of malaria on 23 May 2013.

Artesun® 120mg is indicated for the intravenous or intramuscular treatment of severe malaria caused by *Plasmodium falciparum***.** 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 Artesun® 120mg is the artemisinin derivative artesunate. The API has been well-documented for the treatment of severe malaria.

Intravenous artesunate has been investigated in several clinical trials, chiefly in Southeast Asia, but also in Africa, for the treatment of adults and children with severe *P. falciparum* malaria. These studies have demonstrated significant survival advantage in comparison with intravenous or intramuscular quinine.

The most frequent adverse events during treatment with artesunate were dizziness, lightheadedness, rash, and taste perversion. The most important safety problem with artesunate relates to rare severe allergic reactions involving urticarial rash, hypotension, pruritus, oedema, and dyspnoea.

Based on efficacy and safety data from clinical trials, Artesun® 120mg is acceptable for the intravenous or intramuscular treatment of severe *P. falciparum* malaria.

On the basis of data submitted and public information on the use of parenteral artesunate, the team of assessors has advised that Artesun® 120mg is of acceptable quality, efficacy and safety to allow inclusion of Artesun® 120mg 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 Artesun® 120mg:

	Initial Acceptance					
	Date	**Outcome**	**Date**	**Outcome**	**Date**	**Outcome**
Status on PQ list, i.e. date of listing	23 May 2013	listed				
Dossier Evaluation (Quality assurance)						
Quality	22 April 2013	MR				
Bioequivalence	23 April 2013	MR				
Safety, Efficacy	NA	NA				
Inspection Status						
GMP(re-)inspection						
API	18 July 2012	MR				
FPP	17 Nov 2011	MR				
GCP (re-)inspection	NA	MR				
Batch Analysis	NA	NA				

MR: meets requirements
NA: not applicable, not available