WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Artesun®

International Nonproprietary Names (INN)/strength/pharmaceutical form
Artesunate 60 mg powder for solution for injection

Abstract

Artesun® manufactured at Guilin Pharmaceutical Co. Ltd., No. 43 Qilidian Road, Guilin, Guangxi, China, was accepted for the WHO list of prequalified medicinal products for the treatment of malaria on 5 November 2010.

Artesun® 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® 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® 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® is of acceptable quality, efficacy and safety to allow inclusion of Artesun® in the list of prequalified medicinal products.

Summary of Prequalification Status for Artesun®:

	Initial Acceptance					
	Date	**Outcome**	**Date**	**Outcome**	**Date**	**Outcome**
Status on PQ list	5 Nov 2010	listed				
Dossier Evaluation						
Quality	August 2010	MR				
Bioequivalence	NA	MR				
Safety, Efficacy	Sept 2010	MR				
Inspection Status						
GMP (re-)inspection						
APIs	Sept 2008	MR				
FPP	Aug 2010	MR				
GCP (re-)inspection	NA					
Batch Analysis	NA					

MR: meets requirements
NA: not applicable, not available