WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA135 trade name][1]

International Nonproprietary Name (INN)/strength/pharmaceutical form:
Artesunate 60mg powder for injection

Abstract

[MA135 TRADE NAME] , manufactured at Ipca Laboratories Limited, Sejavta, Ratlam, Madhya Pradesh, India, was included in the WHO list of prequalified medicinal products for the treatment of malaria on 18 December 2018.

[MA135 TRADE NAME] 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 [MA135 TRADE NAME] is the artemisinin derivative artesunate. The API is well-established and 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, [MA135 TRADE NAME] is acceptable for the intravenous or intramuscular treatment of severe *P. falciparum* malaria

The efficacy and safety profile of artesunate suppositories is established based on clinical experience in the treatment of malaria in children less than 7 years of age.

On the basis of data submitted and public information on the use of parenteral artesunate in antimalarial therapy, the team of assessors advised that [MA135 TRADE NAME] is of acceptable quality, efficacy and safety to allow inclusion of [MA135 TRADE NAME] in the list of prequalified medicinal products.

Summary of Prequalification Status for [MA135 TRADE NAME]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	18 Dec 2018	listed
Dossier Evaluation (Quality assurance)		
Quality	27 Nov 2018	MR
Bioequivalence	28 Nov 2018	MR
Safety, Efficacy	NA	NA
Inspection Status		
GMP(re-)inspection		
API	26 Feb 2016	MR
FPP	30 May 2018	MR

[1]Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility..

GCP/GLP (re-)inspection	NA	NA

MR::meets requirements
NA: not applicable, not available
NA*: Not inspected for GCP/GLP since a biowaiver applies