

WHO Prequalification Programme WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA152 trade name]*

Artesunate + Sodium Bicarbonate + Sodium chloride, 60mg+50mg/mL + 9mg/mL,
powder and solvent for solution for Injection

[MA152 trade name], manufactured at Macleods Pharmaceuticals Limited, Kachigam, Daman, 369 210, India, was included in the WHO list of prequalified medicinal products for the treatment of malaria on 13 April 2021.

[MA152 trade name] is indicated for the intravenous or intramuscular treatment of severe malaria caused by *Plasmodium falciparum*, in adults and children.

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(s) of [MA152 trade name] is artesunate.

The efficacy and safety of artesunate is well established based on extensive clinical experience in the treatment of malaria.

For details on the uses of this product and for side effects and warnings, see Part 4 of this WHOPAR (summary of product characteristics).

On the basis of data submitted and public information on the use of artesunate in malaria, the team of assessors advised that [MA152 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA152 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [MA152 trade name]:

Initial acceptance	Date	Outcome
Status on PQ list	13 April 2021	listed
Quality	06 April 2021	MR
Bioequivalence	07 April 2021	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	04 May 2018	MR
FPP	11 December 2017	MR*
GCP/GLP (re-)inspection	NA	NA
API: active pharmaceutical ingredient FPP: finished pharmaceutical product GCP: good clinical practice [quality standard] GLP: good laboratory practice [quality standard]	GMP: good manufacturing practice [quality standard] MR: meets requirements MR*: desk review (based on recent inspection reports) NA: not applicable, not available PQ: prequalification	

The table represents the status of relevant completed activities only.

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