

**WHO Prequalification Programme  
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)**

**Artesun-Plus® (25mg/67.5mg)\***

International Nonproprietary Names (INN) )/strength/pharmaceutical form:  
artesunate/amodiaquine (as hydrochloride) 25 mg/ 67.5 mg tablets

**Abstract**

Artesun-Plus® (25mg/67.5mg), manufactured at Guilin Pharmaceutical Co. Ltd, Guilin, China was included in the WHO list of prequalified medicinal products for the treatment of malaria on 16 November 2012.

Artesun-Plus® (25mg/67.5mg) is a so called artemisinin-based combination therapy (ACT) for the treatment of uncomplicated cases of malaria due to *Plasmodium falciparum* strains which are susceptible to amodiaquine as well as to artesunate.

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 ingredients (APIs) of Artesun-Plus® (25mg/67.5mg) are the 4-aminoquinoline amodiaquine and the artemisinin derivative artesunate. Each of these APIs, marketed as the therapeutic component of single products, is well-established and documented for the treatment of malaria, especially in combination with each other and with other products. Efficacy and safety of amodiaquine and artesunate in uncomplicated *P. falciparum* malaria have been demonstrated in comparative clinical trials in West and Central Africa and in Madagascar.

The most frequent adverse events observed during treatment were anorexia, abdominal pain, nausea, asthenia, somnolence, insomnia and cough.

The most serious safety concerns with these APIs are asthenia, anaemia and vertigo. Agranulocytosis and hepatotoxicity have been reported with amodiaquine, especially at higher doses and/or during prolonged use.

It is not known whether these toxicities observed with prophylactic use of amodiaquine may also develop after repeated cycles of curative treatment.

The efficacy and safety profile of artesunate and amodiaquine is sufficiently established based on clinical experience in the treatment of malaria.

On the basis of data submitted and public information on the use of artemisinin-based combination therapy in malaria, the team of assessors advised that Artesun-Plus® (25mg/67.5mg) is of acceptable quality, efficacy and safety to allow inclusion of Artesun-Plus® (25mg/67.5mg) in the list of prequalified medicinal products.

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\* 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-Plus® (25mg/67.5mg)**

|   | Initial Acceptance |         |      |         |      |         |
|---|--------------------|---------|------|---------|------|---------|
|   | Date               | Outcome | Date | Outcome | Date | Outcome |
| Status on PQ list,<br>i.e. date of listing    | 16 Nov 2012        | listed  |      |         |      |         |
| <b>Dossier Evaluation (Quality assurance)</b> |                    |         |      |         |      |         |
| Quality                                       | 17 Sept 2012       | MR      |      |         |      |         |
| Bioequivalence                                | 17 Sept 2012       | MR      |      |         |      |         |
| Safety, Efficacy                              | NA                 | NA      |      |         |      |         |
| <b>Inspection Status</b>                      |                    |         |      |         |      |         |
| GMP(re-)inspection                            |                    |         |      |         |      |         |
| APIs  | Aug 2012           | MR      |      |         |      |         |
| FPP   | 26 Feb 2010        | MR      |      |         |      |         |
| GCP/GLP<br>(re)inspection                     | 25 Oct 2012        | MR      |      |         |      |         |
| Batch Analysis                                | NA                 | NA      |      |         |      |         |

MR: meets requirements

NA: not applicable, not available