LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING
Carton Blister Pack

1. Name of the medicinal product

[MA103 trade name]* artesunate and amodiaquine (as hydrochloride) 50 mg/135 mg tablets

artesunate and amodiaquine (as hydrochloride)

2. Statement of active substance

Each tablet contains 50 milligrams of artesunate and amodiaquine hydrochloride equivalent to 135 milligrams of amodiaquine.

3. List of excipients

Contains lactose. See patient information leaflet for further information.

4. Pharmaceutical form and contents

3 tablets (1x3)

75 tablets (25x3)

5. Method and route of administration

Oral use

Read the patient information leaflet before use.

6. Special warning that the medicinal product must be stored out of the reach and sight of children

Keep of the sight and reach of children.

7. Other special warning(s), if necessary

8. Expiry date

EXP {MM/YYYY}

9. Special storage conditions

Do not store above 30°C.

10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate

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

11. Name and address of the supplier

Cipla Limited
Cipla House,
Peninsula Business Park,
Ganpatrao Kadam Marg,
Lower Parel, Mumbai- 400013,
India
Phone: +91-22-24826000
Fax: +91-22-24826120

12. WHO Reference Number (Prequalification Programme)

MA103

13. Manufacturer's batch number

<Batch> <Lot> {number}

14. (Advice on) General classification for supply

Medicinal product subject to medical prescription.

15. Instructions on use

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIP

Blister Pack

1. **Name of the medicinal product**

   [MA103 trade name] artesunate and amodiaquine (as hydrochloride) 50 mg/135 mg tablets

   artesunate and amodiaquine (as hydrochloride)

2. **Name of the supplier**

   Cipla Limited

3. **Expiry date**

   EXP {MM/YYYY}

4. **Manufacturer's batch number**

   <Batch> <Lot>{number}

5. **Other**