

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON (Blister)

1. Name of the medicinal product

[MA133 trade name]* Artesunate/amodiaquine (as hydrochloride) 50 mg/135 mg tablets
Artesunate and Amodiaquine (as hydrochloride)

2. Statement of active substance

Each tablet contains 135 mg Amodiaquine (as hydrochloride) and 50mg Artesunate

3. List of excipients

Each tablet contains mannitol.

4. Pharmaceutical form and contents

3 Tablets (1 x 3 Tablets)

30 Tablets (10 x 3 Tablets)

75 Tablets (25 x 3 Tablets)

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 this medicine out 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.

Store tablets in blisters in the provided carton.

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

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

11. Name and address of the supplier

Micro Labs Limited
#31, Race Course Road
Bengaluru -560001
Karnataka, India

12. WHO Reference Number (Prequalification Programme)

MA133

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

1. Name of the medicinal product

[MA133 trade name] Artesunate/amodiaquine (as hydrochloride) 50 mg/135 mg tablets
Artesunate and amodiaquine (as hydrochloride)

2. Name of the supplier

Micro Labs Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other