

## **LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING  
CARTON (Blister)**

**1. Name of the medicinal product**

[MA132 trade name]\*

Artesunate/amodiaquine (as hydrochloride) 25mg/67.5mg tablets

**2. Statement of active substance**

Each tablet contains 67.5 mg Amodiaquine (as hydrochloride) and 25mg 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**

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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**

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

**12. WHO Reference Number (Prequalification Programme)**

MA132

**13. Manufacturer's batch number**

<Batch> <Lot> {number}

**14. (Advice on) General classification for supply**

<To be decided by the national medicines regulatory authority in accordance with national legislation.>

**15. Instructions on use**

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIP**

Blister

**1. Name of the medicinal product**

[MA132 trade name]

Artesunate/amodiaquine (as hydrochloride) 25mg/67.5mg tablets

**2. Name of the supplier**

Micro Labs Limited

**3. Expiry date**

EXP {MM/YYYY}

**4. Manufacturer's batch number**

<Batch> <Lot>{number}

**5. Other**