Amodiaquine (as hydrochloride)/artesunate
270 mg/100 mg tablets
(Micro Labs Ltd), MA134

WHOPAR Part 5

September 2019

LABELLING

Amodiaquine (as hydrochloride)/artesunate   WHOPAR Part 5   September 2019
270 mg/100 mg tablets
(Micro Labs Ltd), MA134

PARTICULARS TO APPEAR ON THE OUTER PACKAGING
CARTON (Blister)

1. **Name of the medicinal product**

   [MA134 trade name][*]

   Artesunate/amodiaquine (as hydrochloride) 100 mg/270 mg tablets

2. **Statement of active substance**

   Each tablet contains 270 mg Amodiaquine (as hydrochloride) and 100mg Artesunate

3. **List of excipients**

   Each tablet contains mannitol.

4. **Pharmaceutical form and contents**

   3 (1 x 3) Tablets/ 6 (1 x 6) Tablets

   30 (10 x 3) Tablets/ 60 (10 x 6) Tablets

   75 (25 x 3) Tablets/150 (25 x 6) 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.

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11. Name and address of the supplier

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

12. WHO Reference Number (Prequalification Programme)

MA134

13. Manufacturer's batch number

<Batch> <Lot> {number}

14. General classification for supply

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

15. Instructions on use

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MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIP
Blister

1. **Name of the medicinal product**

   [MA134 trade name]

   Artesunate/amodiaquine (as hydrochloride) 100 mg/270 mg 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**