Amodiaquine (as hydrochloride)/artesunate
270 mg/100 mg tablets (Guilin Pharmaceutical Co Ltd),
MA085

WHOPAR Part 5

April 2025

LABELLING

Amodiaquine (as hydrochloride)/artesunate   WHOPAR Part 5   April 2025
270 mg/100 mg tablets (Guilin Pharmaceutical Co Ltd),
MA085

PARTICULARS TO APPEAR ON THE OUTER PACKAGING
Middle carton

1. **Name of the medicinal product**

    [MA085 trade name]* amodiaquine (as hydrochloride)/artesunate 270 mg/100 mg tablets

    Amodiaquine (as hydrochloride)/artesunate

2. **Statement of active substance**

    Each tablet contains 100 mg artesunate and amodiaquine hydrochloride equivalent to 270 mg amodiaquine.

3. **List of excipients**

    See patient information leaflet for further information

4. **Pharmaceutical form and contents**

    Tablets

    1 x 3 tablets

    1 x 6 tablets

    25 x 3 tablets

    6 x 25 tablets

5. **Method and route of administration**

    Oral use.

    Do not chew.

    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 {DD/MM/YYYY}

9. **Special storage conditions**

    Do not store above 30°C.

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

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

11. Name and address of the supplier

Guilin Pharmaceutical Co. Ltd.

No. 43, Qilidian Road

Guilin, Guangxi

541004 Guilin

China

12. WHO Reference Number (Prequalification Programme)

MA085

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

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MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIP

Blisters

1. Name of the medicinal product

[MA085 trade name] Amodiaquine (as hydrochloride)/artesunate 270 mg/100 mg tablets

Amodiaquine (as hydrochloride)/artesunate

2. Name of the supplier

Guilin Pharmaceutical Co., Ltd

3. Expiry date

EXP {DD/MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other