

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Middle carton

1. Name of the medicinal product

[MA084 trade name]* amodiaquine (as hydrochloride)/artesunate 135 mg/50 mg tablets

Amodiaquine (as hydrochloride)/artesunate

2. Statement of active substance

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

3. List of excipients

See patient information leaflet for further information

4. Pharmaceutical form and contents

Tablets

1 x 3 tablets

25 x 3 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.

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

Guilin Pharmaceutical Co. Ltd.
No. 43, Qilidian Road
Guilin, Guangxi
541004 Guilin
China

12. WHO Reference Number (Prequalification Programme)

MA084

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

Blisters

1. Name of the medicinal product

[MA084 trade name] amodiaquine (as hydrochloride)/artesunate 135 mg/50 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