LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING 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 artesunate 135 mg and amodiaquine hydrochloride equivalent to amodiaquine 50 mg.

3. List of excipients

See patient information leaflet for further information.

4. Pharmaceutical form and contents

Tablets

3x25x120 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 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.

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

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)

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 STRIPS

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 {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other