

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[MA117 trade name]* Amodiaquine (as hydrochloride) 153 mg dispersible tablets +
Pyrimethamine/sulfadoxine 25 mg/500 mg dispersible tablets
Amodiaquine (as hydrochloride) + Pyrimethamine/sulfadoxine

2. Statement of active substance

Each amodiaquine (as hydrochloride) dispersible tablet contains 153 mg amodiaquine (as hydrochloride) and each pyrimethamine/ sulfadoxine dispersible tablet contains 25 mg pyrimethamine and 500 mg sulfadoxine.

3. List of excipients

4. Pharmaceutical form and contents

Dispersible tablets
50 x 4

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 {DD/MM/YY}

9. Special storage conditions

Do not store above 30°C, store the tablets in blisters in the provided box/carton. Protect from light

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
China, 541004
Tel.:+86 773 3675053
Fax:+86 773 3675692
E-mail:ra@guilinpharma.com

12. WHO Reference Number (Prequalification Programme)

MA117

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

PVC/Alu blister

1. Name of the medicinal product

[MA117 trade name] Amodiaquine (as hydrochloride) 153 mg dispersible tablets +
Pyrimethamine/sulfadoxine 25 mg/500 mg dispersible tablets

Amodiaquine (as hydrochloride) + Pyrimethamine/sulfadoxine

2. Name of the supplier

Guilin Pharmaceutical Co., Ltd.

3. Expiry date

EXP {DD/MM/YY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other