

## **LABELLING**

## **PARTICULARS TO APPEAR ON THE OUTER PACKAGING CARTON**

### **1. Name of the medicinal product**

[MA083 trade name]\* Amodiaquine (as hydrochloride)/ Artesunate 67.5 mg/ 25 mg Tablets  
Amodiaquine (as hydrochloride) / Artesunate

### **2. Statement of active substance**

Each tablet contains artesunate 25 mg and amodiaquine hydrochloride equivalent to amodiaquine 67.5 mg.

### **3. List of excipients**

See patient information leaflet for further information.

### **4. Pharmaceutical form and contents**

Tablets  
3 x 25 x 120 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.

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\* 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)**

MA083

**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**

[MA083 trade name] Amodiaquine (as hydrochloride)/ Artesunate 67.5 mg/ 25 mg Tablets

**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**