

## **LABELLING**

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

Outer carton

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

[MA195 trade name]\* Artesunate 180 mg powder for injection + arginine 20 mg/mL/ sodium bicarbonate 8.4 mg/mL injection Co pack

Artesunate

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

Each vial contains 180 mg artesunate

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

See patient information leaflet for further information

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

*Artesunate*

Powder for solution for injection

180 mg x 1 vial

*Solvent for reconstitution*

Solution for injection

9 mL x 1 ampoule

### **5. Method and route of administration**

Intravenous/intramuscular

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**

Store below 30°C. Do not refrigerate or freeze. Avoid excursions above 30°C.

Keep the vial and ampoule in the provided carton to protect from light.

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

*Reconstituted solution*

The reconstituted solution should be stored below 30°C and should be used within one hour.

**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 541004  
Guangxi, China.

**12. WHO Reference Number (Prequalification Programme)**

MA195

**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 SMALL IMMEDIATE PACKAGING UNITS

Type I glass vial

**1. Name of the medicinal product and route(s) of administration**

[MA195 trade name] Artesunate 180 mg powder for injection

Artesunate

IM/IV

**2. Method of administration**

IM/IV use

**3. Expiry date**

EXP {DD/MM/YYYY}

**4. Manufacturer's batch number**

<Batch> <Lot> {number}

**5. Contents by weight, by volume, or by unit**

180 mg

**6. Other**

## **MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

Type I glass ampoule

### **1. Name of the medicinal product and route(s) of administration**

[MA195 trade name] arginine 20 mg/mL/ sodium bicarbonate 8.4 mg/mL injection

### **2. Method of administration**

For reconstitution

### **3. Expiry date**

EXP {DD/MM/YYYY}

### **4. Manufacturer's batch number**

<Batch> <Lot> {number}

### **5. Contents by weight, by volume, or by unit**

9 mL

### **6. Other**