

## **LABELLING**

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

Outer carton

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

[MA186 trade name]\* Artesunate 120 mg powder for solution for injection. With sodium bicarbonate 50 mg/mL solution and sodium chloride 9 mg/mL solution.

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

Each vial contains 120 mg artesunate powder for injection

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

This medicine contains sodium.

See patient information leaflet for further information.

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

Powder for solution for injection

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

Intramuscular or intravenous use after reconstitution and dilution

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 {MM/YYYY}

### **9. Special storage conditions**

Store below 30°C. Keep the vial and ampoules in the provided carton to protect the product from light. Do not refrigerate or freeze.

The reconstituted and diluted solutions should be stored below 30°C and the total in-use period should not exceed 1 hour.

### **10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate**

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

**11. Name and address of the supplier**

Ipca Laboratories Limited  
48, Kandivli Industrial Estate  
Kandivli (West), Mumbai  
Maharashtra, 400067  
India

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

MA186

**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

Vial

**1. Name of the medicinal product**

[MA186 trade name] Artesunate 120 mg powder for solution for injection.

**2. Method of administration**

I.M. /I.V. use

**3. Expiry date**

EXP {MM/YYYY}

**4. Manufacturer's batch number**

<Batch> <Lot> {number}

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

120 mg

**6. Other**

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

Solvent ampoule

**1. Name of the medicinal product**

[MA135 trade name]

Sodium bicarbonate 50 mg/mL solution for injection

**2. Method of administration**

For reconstitution.

**3. Expiry date**

EXP {MM/YYYY}

**4. Manufacturer's batch number**

<Batch> <Lot> {number}

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

2 mL

**6. Other**

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

Diluent ampoule

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

Sodium chloride 9mg /mL solution for injection

**2. Method of administration**

For dilution.

**3. Expiry date**

EXP {MM/YYYY}

**4. Manufacturer's batch number**

<Batch> <Lot> {number}

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

10 mL

**6. Other**