

## **LABELLING**

## PARTICULARS TO APPEAR ON THE OUTER PACKAGING

### Vial and Ampoule Carton

#### 1. Name of the medicinal product

[MA194 trade name]\* Artesunate 120 mg powder for injection + Sodium bicarbonate 50 mg/mL solution + 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

##### *Artesunate*

Powder for solution for injection

120 mg x 1 vial

120 mg x 100 vials

##### *Sodium bicarbonate*

Clear solution

1 mL x 2 ampoules

1 mL x 200 ampoules

##### *Sodium chloride*

Clear solution

5 mL x 2 ampoules

5 mL x 200 ampoules

#### 5. Method and route of administration

For Intravenous / Intramuscular 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.

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

**7. Other special warning(s), if necessary**

**8. Expiry date**

EXP {MM/YYYY}

**9. Special storage conditions**

Do not store above 25°C, store in a dry place. Keep the vial and ampoules in the provided carton to protect the products from light. Do not refrigerate or freeze.

The reconstituted and diluted solutions should be stored below 25°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**

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

Macleods Pharmaceuticals Limited  
304 Atlanta Arcade  
Marol Church Road  
Andheri (East), Mumbai  
400 059, India

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

MA194

**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

Glass Vial (USP Type III)

**1. Name of the medicinal product**

[MA194 trade name] Artesunate 120 mg powder for solution for injection  
Artesunate

**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

Glass Ampoule (USP Type I)

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

[MA194 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**

1 mL x 2 ampoules

1 mL x 200 ampoules

**6. Other**

## MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Glass Ampoule (USP Type I)

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

[MA194 trade name] Sodium chloride 9 mg/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**

5 mL x 2 ampoules

5 mL x 200 ampoules

**6. Other**