

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

Sodium bicarbonate

Clear solution

1 mL x 2 ampoules

Sodium chloride

Clear solution

5 mL x 2 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.

7. Other special warning(s), if necessary

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

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

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

6. Other