LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer carton

1. Name of the medicinal product

[MA152 trade name][*]

2. Statement of active substance

Each vial contains 60 mg artesunate powder for injection.

3. List of excipients

Solvent (sodium bicarbonate injection) contains sodium bicarbonate and water for injection.
Diluent (sodium chloride injection) contains sodium chloride and water for injection.

4. Pharmaceutical form and contents

Each box contains 1 vial of Artesunate for injection (60 mg) and
1 ampoule of 1 ml Sodium bicarbonate injection (50mg/ml) and
1 ampoule of 5 ml Sodium chloride injection (9mg/ml).

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 out of the reach and sight of children.

7. Other special warning(s), if necessary

8. Expiry date

EXP {MM/YYYY}

9. Special storage conditions

Do not store above 25°C, in a dry place. Keep the vial and ampoules in the provided carton to protect the product from light. Do not refrigerate or freeze. Avoid excursions above 30°C.

For single use only.

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

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

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)

MA152

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

Powder vial

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

[MA152 trade name]

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

60 mg

6. Other

Sterile

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Solvent ampoule

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

Sodium Bicarbonate Injection

2. List of excipients

Sodium bicarbonate, disodium edetate 0.007%w/v and water for injection

3. Pharmaceutical form and contents

Sodium bicarbonate 50mg/mL Injection

4. Expiry date

EXP {MM/YYYY}

5. Manufacturer's batch number

<Batch> <Lot> {number}

6. Contents by weight, by volume, or by unit

1 mL

7. Other

Sterile

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Diluent ampoule

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

Sodium Chloride Injection

2. List of excipients

Sodium chloride and water for injection

3. Pharmaceutical form and contents

Sodium chloride 9mg/mL Injection

4. Expiry date

EXP {MM/YYYY}

5. Manufacturer's batch number

<Batch> <Lot> {number}

6. Contents by weight, by volume, or by unit

5 mL

7. Other

Sterile