

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[MA200 trade name]* Artesunate 120 mg powder for injection co-packaged with arginine
20 mg/mL / sodium bicarbonate 8.4 mg/mL injection

Artesunate

2. Statement of active substance

Each vial contains 120 mg artesunate powder.

3. List of excipients

Each ampoule of 6 mL solvent contains arginine, sodium bicarbonate, phosphoric acid and water for injection.

4. Pharmaceutical form and contents

Powder and solvent for solution for injection

The pack contains 1 vial of artesunate powder for injection and 1 ampoule of arginine /sodium bicarbonate injection.

5. Method and route of administration

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

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

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

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

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)

MA200

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 and route(s) of administration

[MA200 trade name] Artesunate 120 mg powder for injection

Artesunate

IV/IM use

2. Method of administration

3. Expiry date

EXP {DD/MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot> {number}

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

120mg

6. Other

Sterile

Guilin Pharmaceutical Co., Ltd.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Ampoule

1. Name of the medicinal product and routes of administration

Arginine 20 mg/mL and sodium bicarbonate 8.4 mg/mL injection

Arginine and sodium bicarbonate

IV/IM use

2. Method of administration

For reconstitution of artesunate 120 mg powder for injection

3. Expiry date

EXP {DD/MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot> {number}

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

6 mL

6. Other

Sterile

Guilin Pharmaceutical Co., Ltd.