

Artesunate 60mg powder for solution for injection
(with sodium bicarbonate 8.4mg/mL and arginine
20mg/mL injection)
(Guilin Pharmaceutical Co. Ltd), MA168

WHOPAR Part 5

December 2023

LABELLING

MINIMUM PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Vial and ampoule carton:

1. Name of the medicinal product

[MA168 trade name]* Artesunate 60mg powder for solution for injection (with sodium bicarbonate 8.4mg/mL and arginine 20mg/mL solution for dilution)

2. List of excipients

3. Pharmaceutical form and contents

Artesunate:

Powder for solution for injection
60 mg
x 1 vial

Sodium bicarbonate and arginine

Solution for dilution
3 mL
x 1 ampoule

4. Method and route of administration

For intravenous or intramuscular use.
Read the patient information leaflet before use.

5. Special warning that the medicinal product must be stored out of the reach and sight of children

Keep out of the reach of children.

6. Other special warning(s), if necessary

7. Expiry date

EXP {DD/MM/YYYY}

8. 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.
The reconstituted solution should be stored below 30°C and should be used within one hour.

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

10. Name and address of the supplier

Guilin Pharmaceutical Co., Ltd
No. 43, Qilidian Road, Guilin 541004
Guangxi, China.

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

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11. WHO Reference Number (Prequalification Programme)

MA168

12. Manufacturer's batch number

<Batch> <Lot> {number}

13. (Advice on) General classification for supply

Medicinal product subject to medical prescription.

14. Instructions on use

Read the patient information leaflet before use.

MINIMUM PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING
Vial

- 1. Name of the medicinal product**
[MA168 trade name] Artesunate 60 mg powder for solution for injection
- 2. Method and route of administration**
For intravenous or intramuscular use.
- 3. Expiry date**
EXP {DD/MM/YYYY}
- 4. Name and address of the supplier**
Guilin Pharmaceutical Co., Ltd
- 5. Manufacturer's batch number**
<Batch> <Lot> {number}
- 6. (Advice on) General classification for supply**
Medicinal product subject to medical prescription.

MINIMUM PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

Ampoule

1. Name of the medicinal product

[MA168 trade name] Sodium bicarbonate 8.4mg/mL and arginine 20mg/mL solution for reconstitution

2. Pharmaceutical form and contents

Solution for reconstitution
3mL

3. Expiry date

EXP {DD/MM/YYYY}

4. Name and address of the supplier

Guilin Pharmaceutical Co., Ltd

5. Manufacturer's batch number

<Batch> <Lot> {number}

6. (Advice on) General classification for supply

Medicinal product subject to medical prescription.