LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer Carton

1. NAME OF THE MEDICINAL PRODUCT

Artesun® 120mg [*]

2. STATEMENT OF ACTIVE SUBSTANCE

Each vial contains 120 mg artesunate powder for injection.

3. LIST OF EXCIPIENTS

Artesunate powder for injection does not contain any 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 (120 mg) and
1 ampoule of 2 ml Sodium bicarbonate injection (50mg/ml) and
1 ampoule of 10 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 SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

[*] Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

EXP {MM/YYYY}

9. SPECIAL STORAGE CONDITIONS

Store below 30°C. Protect from light.
The reconstituted solution should be stored below 30°C and should be used within one 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

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

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

MA090

13. MANUFACTURER'S BATCH NUMBER

Batch {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

Artesun® 120mg
Artesunate for injection

2. METHOD OF ADMINISTRATION

I.M./I.V. USE

3. EXPIRY DATE

EXP {DD/MM/YYYY}

4. MANUFACTURER'S BATCH NUMBER

Batch {number}

5. CONTENTS BY WEIGHT, BY VOLUME, OR BY UNIT

120 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 (50 mg/ampoule)
Water for injections (2 ml/ampoule)

3. PHARMACEUTICAL FORM AND CONTENTS

Sodium Bicarbonate Injection
2 ml
100 mg (50 mg/ml)

4. EXPIRY DATE

EXP {DD/MM/YYYY}

5. MANUFACTURER'S BATCH NUMBER

Batch {number}

5. CONTENTS BY WEIGHT, BY VOLUME, OR BY UNIT

2 ml

6. 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 (90 mg/ampoule)
Water for injections (10 ml/ampoule)

3. PHARMACEUTICAL FORM AND CONTENTS

Sodium Chloride Injection
10 ml
90 mg (9 mg/ml)

4. EXPIRY DATE

EXP {DD/MM/YYYY}

5. MANUFACTURER'S BATCH NUMBER

5. CONTENTS BY WEIGHT, BY VOLUME, OR BY UNIT

10 ml

6. OTHER

Sterile