

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton (pack of 1 vial and 2 ampoules)

1. NAME OF THE MEDICINAL PRODUCT

Artesun*

2. STATEMENT OF ACTIVE SUBSTANCE

Each vial contains 60 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 (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

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

8. EXPIRY DATE

EXP {DD/MM/YYYY}

9. SPECIAL STORAGE CONDITIONS

Do not store above 30°C. Store in the original container protected from light.
Reconstituted and diluted solution should be stored below 30°C and used within 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

Guilin Pharmaceutical Co., Ltd.
No. 43 Qilidian Road
Guilin
Guangxi
China
TEL : + 86 773 3675053
Fax: +86 773 2670530
Manufacture site: No. 43 Qilidian Road, Guilin Guangxi,China

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

MA051

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®
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

60 mg

6. OTHER

Sterile

Mfg.: Guilian Pharmaceutical Co., Ltd.

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 (1 ml/ampoule)

3. PHARMACEUTICAL FORM AND CONTENTS

Sodium Bicarbonate Injection
1ml
50mg (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

1 ml

6. OTHER

Sterile

Mfg.: Guilian Pharmaceutical Co., Ltd.

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 (45 mg/ampoule)

Water for injections (5 ml/ampoule)

3. PHARMACEUTICAL FORM AND CONTENTS

Sodium Chloride Injection

5ml

45mg (9 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

5 ml

6. OTHER

Sterile

Mfg.: Guilian Pharmaceutical Co., Ltd.