

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton (pack of 1 vial and 2 ampoules)

1. NAME OF THE MEDICINAL PRODUCT

[MA135 trade name]¹

2. STATEMENT OF ACTIVE SUBSTANCE

Artesunate for injection Ph.Int. 60mg

3. LIST OF EXCIPIENTS

Artesunate for injection Ph.Int. 60mg contains no excipients
Solvent (Sodium bicarbonate Injection BP 5% w/v) contains sodium bicarbonate and water
Diluent (Sodium chloride injection BP 0.9%w/v) contains sodium chloride and water

4. PHARMACEUTICAL FORM AND CONTENTS

Each combination pack contains:
Artesunate Ph. Int. (sterile) 60 mg
Sodium bicarbonate Injection BP 5% w/v and
Sodium chloride Injection BP 0.9%w/v

5. METHOD AND ROUTE OF ADMINISTRATION

Intramuscular (IM) or intravenous (IV) 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 of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

¹Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

EXP {MM/YYYY}

9. SPECIAL STORAGE CONDITIONS

Store below 30°C. 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.

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

Ipca Laboratories Limited
48, Kandivli Industrial Estate
Kandivli (W), Mumbai 400067
India

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

MA135

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

[MA135 trade name]
Artesunate for injection Ph.Int 60mg

2. NAME OF THE SUPPLIER

Ipca Laboratories Limited

3. EXPIRY DATE

EXP {MM/YYYY}

4. MANUFACTURER'S BATCH NUMBER

Batch {number}

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

60 mg

6. OTHER

Sterile
For IM/IV use only

Mfg: Ipca Laboratories Limited

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Solvent ampoule

1. NAME OF THE MEDICINAL PRODUCT

[MA135 trade name]
Sodium Bicarbonate Injection BP 5% w/v

2. LIST OF EXCIPIENTS

Sodium Bicarbonate BP 5% w/v
Water for Injections BP

3. PHARMACEUTICAL FORM AND CONTENTS

1ml Sodium Bicarbonate Injection 5% w/v (50 mg/ml)

4. EXPIRY DATE

EXP {DD/MM/YYYY}

5. MANUFACTURER'S BATCH NUMBER

Batch {number}

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

1 ml

7. OTHER

Sterile

Mfg: Ipca Laboratories Limited

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Diluent ampoule

1. NAME OF THE MEDICINAL PRODUCT

[MA135 trade name]
Sodium Chloride Injection BP 0.9% w/v

2. LIST OF EXCIPIENTS

Sodium Chloride BP 0.9% w/v
Water for Injections BP

3. PHARMACEUTICAL FORM AND CONTENTS

5ml Sodium Chloride Injection 0.9% w/v (9 mg/ml)

4. EXPIRY DATE

EXP {DD/MM/YYYY}

5. MANUFACTURER'S BATCH NUMBER

Batch {number}

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

5 ml

7. OTHER

Sterile

Mfg: Ipca Laboratories Limited