

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton label

1. Name of the medicinal product

[MA124 trade name]*

Artesunate 100 mg rectal soft capsules

2. Statement of active substance

Each rectal capsule contains 100 mg artesunate.

3. List of excipients

See patient information leaflet for further information.

4. Pharmaceutical form and contents

Rectal soft capsule

1 × 2 rectal capsules

5. Method and route of administration

Rectal

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

EXP {MM/YYYY}

9. Special storage conditions

Do not freeze or refrigerate. Do not store above 25°C. 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

Cipla Limited
Cipla House
Peninsula Business Park
Ganpatrao Kadam Marg

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

Lower Parel
Mumbai: 400013
India

12. WHO Reference Number (Prequalification Programme)

MA124

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 BLISTERS

Alu-Alu Blister

1. Name of the medicinal product

[MA124 trade name]

Artesunate 100 mg rectal soft capsules

2. Name of the supplier

Cipla Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other