

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton label

1. Name of the medicinal product

[MA123 trade name]* artesunate 100 mg soft gelatin rectal capsules

Artesunate

2. Statement of active substance

Each soft gelatin rectal capsules contains 100 mg artesunate

3. List of excipients

See patient information leaflet for further information.

4. Pharmaceutical form and contents

Soft gelatin rectal capsules

1 x 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 this medicine out of the sight and reach of children.

7. Other special warning(s), if necessary

8. Expiry date

EXP {MM/YYYY}

9. Special storage conditions

Store at 25° C (77° F); excursions permitted to 15° to 30° C (59° to 86°F). Avoid excursions over 30°C. Do not freeze.

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

Strides Pharma Global Pte. Limited

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

1 Gateway Drive
#06-06
Westgate Tower
Singapore 608531

12. WHO Reference Number (Prequalification Programme)

MA123

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 OR STRIP

Alu-alu Blister

1. Name of the medicinal product

[MA123 trade name] artesunate 100 mg soft gelatin rectal capsules

Artesunate

2. Name of the supplier

Strides Pharma Science Limited

3. Expiry date

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other