LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[MA088 trade name]*

Artemether/Lumefantrine 20 mg/120 mg Tablets

2. Statement of active substance

Each tablet contains 20 mg artemether and 120 mg lumefantrine.

3. List of excipients

See patient information leaflet for further information.

4. Pharmaceutical form and contents

Tablets

4 x 6 tablets

1x6 tablets

1x12 tablets

1x18 tablets

1x24 tablets

30x6 tablets

30x12 tablets

30x18 tablets

30x24 tablets

5. Method and route of administration

Oral use.

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 store above 30°C. Store tablets in the blisters in the provided carton.

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

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 1 Gateway Drive #06-06 Westgate Tower Singapore 608531

12. WHO Reference Number (Prequalification Programme)

MA088

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

PVC/PE/PVDC-Alu blisters

1. Name of the medicinal product

[MA088 trade name]

Artemether/Lumefantrine 20 mg/120 mg Tablets

2. Name of the supplier

Strides Pharma Global Pte. Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other