LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer carton / mono carton

1.   Name of the medicinal product

[MA110 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

4.   Pharmaceutical form and contents

Dispersible tablet

6 tablets per blister card, 1 blister card per mono carton. 30 mono cartons in an outer carton.

12 tablets per blister card, 1 blister card per mono carton. 30 mono cartons in an outer carton.

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 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 below 30°C. Avoid excursions above 30°C. Protect from light and moisture.

Store tablets in blisters in the provided carton.

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* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.
# Formerly known as 'Strides Shasun Limited'.

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
3, Tuas South Avenue 4
Singapore-637610
Tel. No.: + (65) 6708 8505
Fax No.: + (65) 6708 8506

12. WHO Reference Number (Prequalification Programme)

MA110

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

Blisters

1. **Name of the medicinal product**

    [MA110 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**