LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer carton

1. **Name of the medicinal product**

   [MA137 trade name]*Artemether/lumefantrine 20mg/120mg dispersible tablets
   Artemether/lumefantrine

2. **Statement of active substance**

   Each dispersible 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, 17 blisters per carton.
   6 tablets per blister card, 30 blisters per carton.
   12 tablets per blister card, 30 blisters per 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**

   Do not store above 30°C. Protect from light. Avoid excursions above 30°C.

10. **Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate**

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

11. Name and address of the supplier

Macleods Pharmaceuticals Limited
304, Atlanta Arcade
Marol Church Road
Andheri (East)
Mumbai -400 059, India
Tel. No.: +(91) 22 66762800
Fax No.: +(91) 22 28216599

12. WHO Reference Number (Prequalification Programme)

MA137

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**

    [MA137 trade name] Artemether/lumefantrine 20mg/120mg dispersible tablets
    Artemether/lumefantrine

2. **Name of the supplier**

    Macleods Pharmaceuticals Limited

3. **Expiry date**

    EXP {MM/YYYY}

4. **Manufacturer's batch number**

    <Batch><Lot>{number}

5. **Other**