LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer carton

1. Name of the medicinal product

[MA091 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 the patient information leaflet for further information.

4. Pharmaceutical form and contents

Uncoated tablet.

6 tablets per blister card; 1, 2, 3, 4 or 30 such blister cards per carton

8 tablets per blister card; 3 such blister cards per carton

12 tablets per blister card; 1, 2 or 30 such blister cards per carton

18 tablets per blister card; 1 or 30 such blister cards per carton

24 tablets per blister card; 1 or 30 such blister cards 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.

[*] 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

Macleods Pharmaceuticals Limited
304, Atlanta Arcade
Marol Church Road
Andheri (East)
Mumbai – 400 059
India
Tel: +91-22-66762800
Fax: +91 -22-28216599

12. WHO Reference Number (Prequalification Programme)

MA091

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

Blister cards

1. Name of the medicinal product

[MA091 trade name]

Artemether/lumefantrine 20 mg/120 mg tablets

2. Name of the supplier

Macleods Pharmaceuticals Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other