

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[MA100 trade name]* artemether/lumefantrine 40mg/240mg tablets

2. Statement of active substance

Each tablet contains 40 mg artemether and 240 mg lumefantrine.

3. List of excipients

4. Pharmaceutical form and contents

Tablet

1 x 12 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 in the original container.

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

No special requirements.

Any unused product or waste material should be disposed of in accordance with local requirements.

11. Name and address of the supplier

Mylan Laboratories Limited

Plot No. 564/A/22, Road No.92, Jubilee Hills

Hyderabad - 500096, Telangana, India

12. WHO Reference Number (Prequalification Programme)

MA100

13. Manufacturer's batch number

<Batch> <Lot> {number}

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

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

[MA100 trade name] artemether/lumefantrine 40mg/240mg tablets

2. Name of the supplier

Mylan Laboratories Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot> {number}

5. Other