

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[MA099 trade name]* artemether/lumefantrine 20mg/120mg tablets

Artemether/lumefantrine

2. Statement of active substance

Each tablet contains 20mg artemether and 120mg lumefantrine

3. List of excipients

4. Pharmaceutical form and contents

Tablets

6x1

6x2

6x3

6x4

18x1

24x1

18x10

24x10

18x30

24x30

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. Store in the original container.

* 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

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)

MA099

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

[MA099 trade name] artemether/lumefantrine 20mg/120mg tablets

Artemether/lumefantrine

2. Name of the supplier

Mylan Laboratories Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other