

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[MA092 trade name]*

Artemether/Lumefantrine 20 mg/120 mg dispersible tablets

2. Statement of active substance

Each tablet contains 20 mg artemether and 120 mg lumefantrine.

3. List of excipients

Contains aspartame

4. Pharmaceutical form and contents

1 x 6 dispersible tablets

30 x 6 dispersible tablets

1 x 12 dispersible tablets

30 x12 dispersible 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 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 package in the outer carton.

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

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

11. Name and address of the supplier

Ajanta Pharma Ltd.
Ajanta Tower
54-A, M VasANJI Road
Chakala
Andheri (E)
Mumbai – 400 093
India.

12. WHO Reference Number (Prequalification Programme)

MA092

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

PVC/PVdC-aluminium blister

1. Name of the medicinal product

[MA092 trade name]

Artemether/Lumefantrine 20 mg/120 mg dispersible tablets

2. Name of the supplier

Ajanta Pharma Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other