

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer carton

1. Name of the medicinal product

[MA111 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.

1 x 6 tablets

1 x 12 tablets

1 x 18 tablets

1 x 24 tablets

30 x 6 tablets

30 x 12 tablets

30 x 18 tablets

30 x 24 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. 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

Ajanta Pharma Ltd.
Ajanta House
Charkop
Kandivli (West)
Mumbai – 400 067
India

12. WHO Reference Number (Prequalification Programme)

MA111

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-Alu blisters

1. Name of the medicinal product

[MA111 trade name]

Artemether/lumefantrine 20 mg/120 mg tablets

2. Name of the supplier

Ajanta Pharma Ltd.

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other