

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[MA128 trade name]* Artemether/lumefantrine 40 mg/240 mg tablets
Artemether/lumefantrine

2. Statement of active substance

Each tablet contains 40 mg artemether and 240 mg lumefantrine.

3. List of excipients

See patient information leaflet for further information

4. Pharmaceutical form and contents

Tablet

1 x 6 tablets

30 x 6 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 order to protect the product from light.

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

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

Kandivli (West)
Mumbai – 400 067
India

12. WHO Reference Number (Prequalification Programme)

MA128

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

PVC/PVdC-Alu blisters

1. Name of the medicinal product

[MA128 trade name] Artemether/lumefantrine 40 mg/240 mg tablets

Artemether/lumefantrine

2. Name of the supplier

Ajanta Pharma Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other