

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Blister carton

1. Name of the medicinal product

[MA129 trade name]* Artemether/lumefantrine 60 mg/360 mg tablets
Artemether/lumefantrine

2. Statement of active substance

Each tablet contains 60 mg artemether and 360 mg lumefantrine

3. List of excipients

See patient information leaflet for further information.

4. Pharmaceutical form and contents

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
Kandivli (West)
Mumbai – 400 067

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

India

12. WHO Reference Number (Prequalification Programme)

MA129

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

Blisters

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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