

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton (Alu-Alu blister pack)

1. Name of the medicinal product

[MA136 trade name]*Artemether/lumefantrine 20mg/120mg dispersible tablets
Artemether/lumefantrine

2. Statement of active substance

Each dispersible tablet contains 20 mg artemether and 120 mg lumefantrine.

3. List of excipients

4. Pharmaceutical form and contents

Dispersible tablet

1 × 6 tablets

1 × 12 tablets

30 × 6 tablets

30 × 12 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.

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

Ipca Laboratories Limited
48, Kandivli Industrial Estate
Kandivli (West)
Mumbai 400 067
India

12. WHO Reference Number (Prequalification Programme)

MA136

13. Manufacturer's batch number

<Batch> {number}

14. (Advice on) General classification for supply

Medicinal product subject to medical prescription.

15. Instructions on use

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton (PVC/PCTFE/PVC-Alu blister pack)

1. Name of the medicinal product

[MA136 trade name]* Artemether/lumefantrine 20mg/120mg dispersible tablets
Artemether/lumefantrine

2. Statement of active substance

Each dispersible tablet contains 20 mg artemether and 120 mg lumefantrine.

3. List of excipients

4. Pharmaceutical form and contents

Dispersible tablet

1 × 6 tablets

1 × 12 tablets

30 × 6 tablets

30 × 12 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. Store tablets in blisters in the provided carton.

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

Ipca Laboratories Limited
48, Kandivli Industrial Estate
Kandivli (West)
Mumbai 400 067
India

12. WHO Reference Number (Prequalification Programme)

MA136

13. Manufacturer's batch number

<Batch> {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

Alu-Alu blister pack and PVC/PCTFE/PVC-Alu blister pack

1. Name of the medicinal product

[MA136 trade name] Artemether/lumefantrine 20 mg/120 mg dispersible tablets
Artemether/lumefantrine

2. Name of the supplier

Ipca Laboratories Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> {number}

5. Other