

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer carton (PVC/Aclar/PVC-Alu blisters)

1. Name of the medicinal product

[MA121 trade name]*

Artemether/lumefantrine 60 mg/360 mg tablets

2. Statement of active substance

Each tablet contains 60 mg artemether and 360 mg lumefantrine.

3. List of excipients

See the patient information leaflet for further information.

4. Pharmaceutical form and contents

Tablets

1 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 out of the 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.

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

Cipla Ltd

Cipla House

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

Peninsula Business Park
Ganpatrao Kadam Marg
Lower Parel
Mumbai, Maharashtra, 400 013
India

12. WHO Reference Number (Prequalification Programme)

MA121

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/Aclar/PVC-Alu blisters

1. Name of the medicinal product

[MA121 trade name]

Artemether/lumefantrine 60 mg/360 mg tablets

2. Name of the supplier

Cipla Ltd

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other