

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Blister carton

1. Name of the medicinal product

[MA064 trade name]* Artemether / Lumefantrine 20mg/120mg tablets

2. Statement of active substance

Each tablet contains artemether 20 mg and lumefantrine 120 mg

3. List of excipients

See patient information leaflet for further information.

4. Pharmaceutical form and contents

Tablets

Aluminium-aluminium blister pack:

1 x 6 tablets

2 x 6 tablets

3 x 6 tablets

4 x 6 tablets

Aluminium- Aclar blister pack:

1 x 6 tablets

1 x 12 tablets

1 x 18 tablets

1 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. Store in the original package.

* 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

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

12. WHO Reference Number (Prequalification Programme)

MA064

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

- 1. Name of the medicinal product**
[MA064 trade name] Artemether / Lumefantrine 20mg/120mg tablets
- 2. Name of the supplier**
Cipla Ltd
- 3. Expiry date**
EXP {MM/YYYY}
- 4. Manufacturer's batch number**
<Batch> <Lot>{number}
- 5. Other**