

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[MA155 trade name]* Artemether/lumefantrine 60 mg/360 mg dispersible tablets
Artemether/Lumefantrine

2. Statement of active substance

Each tablet contains 60 mg artemether and 360 mg lumefantrine

3. List of excipients

4. Pharmaceutical form and contents

Dispersible tablets

1 × 6 tablets

20 × 1 × 6 tablets

30 × 1 × 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 tablets in the blisters in the provided carton.

10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate

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

11. Name and address of the supplier

Guilin Pharmaceutical Co., Ltd.
No. 43, Qilidian Road
Guilin 541004
Guangxi
China

12. WHO Reference Number (Prequalification Programme)

MA155

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 blister

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Artemether/lumefantrine

2. Name of the supplier

Guilin Pharmaceutical Co., Ltd.

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other