

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[MA165 trade name]* Artemether / Lumefantrine 80 mg /480 mg Tablets

2. Statement of active substance

Each tablet contains 80 mg artemether and 480 mg lumefantrine

3. List of excipients

See patient information leaflet for further information.

4. Pharmaceutical form and contents

Tablets

6 x 20 x 70 tablets

6 x 640 tablets

6 x 30 x 40 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

11. Name and address of the supplier

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

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

Guangxi, China.

12. WHO Reference Number (Prequalification Programme)

MA165

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

Alu-PVC/PVdC blisters

1. Name of the medicinal product

[MA165 trade name][†] Artemether / Lumefantrine 80 mg / 480 mg Tablets

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

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