LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING
Carton

1. Name of the medicinal product

[MA164 trade name]* Artemether / Lumefantrine 20 mg /120 mg Tablets

2. Statement of active substance

Each tablet contains 20 mg artemether and 120 mg lumefantrine

3. List of excipients

See patient information leaflet for further information.

4. Pharmaceutical form and contents

Tablets
24 x 20 x 48 tablets
6 x 1 x 900 tablets
12 x 1 x 900 tablets
18 x 1 x 900 tablets
24 x 1 x 750 tablets
6 x 30 x 50 tablets
12 x 30 x 50 tablets
18 x 30 x 50 tablets
24 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.

* 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

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

12. WHO Reference Number (Prequalification Programme)

MA164

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

[MA164 trade name][†] Artemether / Lumefantrine 20 mg / 120 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

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