

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton label

1. Name of the medicinal product

[MA151 trade name]* Dihydroartemisinin /Piperaquine phosphate 60 mg/480 mg Tablets
Dihydroartemisinin /Piperaquine phosphate

2. Statement of active substance

Each tablet contains 60 mg dihydroartemisinin and 480 mg piperaquine phosphate

3. List of excipients

See patient information leaflet for further information.

4. Pharmaceutical form and contents

Film-coated Tablets

25 × 6, 1 × 6

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 {DD/MM/YYYY}

9. Special storage conditions

Store in tightly closed containers, protected from light and moisture, not above 25°C.

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)

MA151

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

Blister

1. Name of the medicinal product

[MA151 trade name] Dihydroartemisinin /Piperaquine phosphate 60mg/480mg Tablets
Dihydroartemisinin /Piperaquine phosphate

2. Name of the supplier

Guilin Pharmaceutical Co., Ltd

3. Expiry date

EXP {DD/MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other