

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton label

1. Name of the medicinal product

[MA139 trade name] Dihydroartemisinin /piperazine phosphate 40 mg/320 mg dispersible tablets

Dihydroartemisinin /piperazine phosphate

2. Statement of active substance

Each dispersible tablet contains dihydroartemisinin 40 mg and piperazine phosphate 320 mg

3. List of excipients

4. Pharmaceutical form and contents

Dispersible tablets

2 x 3 tablets

25 x 3 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 {DD/MM/YYYY}

9. Special storage conditions

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

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)

MA139

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

PA/Alu /PVC-Alu blister

1. Name of the medicinal product

[MA139 trade name]* Dihydroartemisinin /piperaquine phosphate 40 mg/320 mg dispersible 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