WHOPAR Part 5

Updated: May 2021

LABELLING

Updated: May 2021

PARTICULARS TO APPEAR ON THE OUTERPACKAGING

Carton label

1. Name of the medicinal product

[MA151 trade name] *

Dihydroartemisinin / Piperaquine (as phosphate) 60 mg/480 mg Tablets

2. Statement of active substance

Each tablet contains 60 mg dihydroartemisinin and 480 mg piperaquine (as phosphate)

3. List of excipients

See patient information leaflet for further information.

4. Pharmaceutical form and contents

Tablets

25 x 6

1 x 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 out of the reach of children.

7. Other special warning(s), if necessary

8. Expiry date

EXP {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

Page 2 of 4

Dihydroartemisinin /Piperaquine (as phosphate) 60mg/480mg Tablets (Guilin

WHOPAR Part 5

Updated: May 2021

Pharmaceuticals Co. Ltd), MA151 *Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

Updated: May 2021

Dihydroartemisinin/Piperaquine (as phosphate) 60mg/480mg Tablets (Guilin Pharmaceuticals Co. Ltd), MA151

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

Updated: May 2021

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIP Aluminium strip pack

1. Name of the medicinal product

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

2. Name of the supplier

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

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other