

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[MA177 trade name]* Dihydroartemisinin/piperaquine 40 mg/320 mg tablets
Dihydroartemisinin/piperaquine

2. Statement of active substance

Each film-coated tablet contains 40 mg dihydroartemisinin and 320 mg piperaquine (as phosphate)

3. List of excipients

Contains FD&C yellow #6/sunset yellow FCF aluminium lake

4. Pharmaceutical form and contents

Tablets, film-coated

2x6x1

1x6x1

1x6x25

1x9x1

1x9x25

1x3x25

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

Do not store above 25°C. Store in the original pack in a place protected from light and humidity.

* 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

Beijing Holley-Cotec Pharmaceuticals Co. Ltd
Building 8, (3-3) 6 Langjiayuan
Chaoyang District
Beijing
China

12. WHO Reference Number (Prequalification Programme)

MA177

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 POUCH

PET/Alu/PE pouch

1. Name of the medicinal product

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Dihydroartemisinin/piperaquine

2. Name of the supplier

Beijing Holley-Cotec Pharmaceuticals Co., Ltd

3. Expiry date

EXP DD/MM/YYYY

4. Manufacturer's batch number

<Batch> <Lot> {number}

5. Other

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MINIMUM PARTICULARS TO APPEAR ON BLISTERS

PVC/Aluminium blister

1. Name of the medicinal product

[MA177 trade name] Dihydroartemisinin/piperaquine 40 mg/320 mg tablets
Dihydroartemisinin/piperaquine

2. Name of the supplier

Beijing Holley-Cotec Pharmaceuticals Co., Ltd

3. Expiry date

EXP {DD/MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot> {number}

5. Other