

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer carton for blister

1. Name of the medicinal product

[MA178 trade name]* Pyrimethamine/sulfadoxine 12.5mg/250mg dispersible tablet
Pyrimethamine/sulfadoxine

2. Statement of active substance

Each dispersible tablet contains 12.5 mg pyrimethamine and 250 mg sulfadoxine

3. List of excipients

4. Pharmaceutical form and contents

Dispersible tablet

1 blister card per box, 450 boxes per carton.

10 blister cards per box, 140 boxes per carton.

50 blister cards per box, 48 boxes per carton.

100 blister cards per box, 24 boxes per carton.

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 box/carton. Protect from light.

* 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)

MA178

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

PVC-Alu blister

1. Name of the medicinal product

[MA178 trade name] Pyrimethamine/sulfadoxine 12.5mg/250mg dispersible tablet
Pyrimethamine/sulfadoxine

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

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE bottle label/Outer carton

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[MA178 trade name][†] Pyrimethamine/sulfadoxine 12.5mg/250mg dispersible tablet
Pyrimethamine/sulfadoxine

2. Statement of active substance

Each dispersible tablet contains 12.5 mg pyrimethamine and 250 mg sulfadoxine

3. List of excipients

4. Pharmaceutical form and contents

Dispersible tablet

1 x 100

1 x 1000

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 box/carton. Protect from light.

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