**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.

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* 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**