

## **LABELLING**

## **PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

Carton (Alu/PVC blister card)

### **1. Name of the medicinal product**

[MA113 trade name]\*

Pyrimethamine/Sulfadoxine 25 mg/500 mg tablets

### **2. Statement of active substance**

Each tablet contains 25 mg of pyrimethamine and 500 mg of sulfadoxine

### **3. List of excipients**

Contains lactose

### **4. Pharmaceutical form and contents**

Tablets

1 x 3 tablets

10 x3 tablets

50 x3 tablets

100 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 {MM/YYYY}

### **9. Special storage conditions**

Do not store above 30°C. Store the tablets in blisters in the provided box or carton.

### **10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate**

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\* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

**11. Name and address of the supplier**

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

**12. WHO Reference Number (Prequalification Programme)**

MA113

**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**

Alu/PVC blister card

**1. Name of the medicinal product**

[MA113 trade name]

Pyrimethamine/Sulfadoxine 25 mg/500 mg tablets

**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 IMMEDIATE PACKAGING**

HDPE Bottle with 2gm or 1gm silica gel desiccant

### **1. Name of the medicinal product**

[MA113 trade name]<sup>†</sup>

Pyrimethamine/Sulfadoxine 25 mg/500 mg tablets

### **2. Statement of active substance**

Each tablet contains 25 mg of pyrimethamine and 500 mg of sulfadoxine

### **3. List of excipients**

Contains lactose

### **4. Pharmaceutical form and contents**

Tablet

100 tablets

1000 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 {MM/YYYY}

### **9. Special storage conditions**

Do not store above 30°C. Store in the original container.

### **10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate**

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<sup>†</sup> Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

**11. Name and address of the supplier**

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

**12. WHO Reference Number (Prequalification Programme)**

MA113

**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**