

## **LABELLING**

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

Outer carton

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

[MA144 trade name]\*

Sulfadoxine & pyrimethamine dispersible tablets 250/12.5 mg

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

Each uncoated dispersible tablet contains 12.5 mg pyrimethamine and 250 mg sulfadoxine.

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

Each tablet contains isomalt.

See the patient information leaflet for further information.

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

Dispersible tablets

1 × 3 tablets

10 × 3 tablets

25 × 3 tablets

50 × 3 tablets

100 × 3 tablets

11 × 10 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 out of the reach and sight of children.

### **7. Other special warning(s), if necessary**

### **8. Expiry date**

EXP {MM/YYYY}

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

**9. Special storage conditions**

Do not store above 30°C. Store tablets in blisters in the provided carton in order to protect from light.

**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**

S Kant Healthcare Ltd  
3-A Shiv Sagar Estate  
North Wing  
Dr Annie Besant Road  
Worli, Mumbai 400 018  
India

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

MA144

**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/PVDC blisters

**1. Name of the medicinal product**

[MA144 trade name]

Sulfadoxine & pyrimethamine dispersible tablets 250/12.5 mg

**2. Name of the supplier**

S Kant Healthcare Ltd

**3. Expiry date**

EXP {MM/YYYY}

**4. Manufacturer's batch number**

<Batch> <Lot> {number}

**5. Other**