

## **LABELLING**

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

HDPE bottle label

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

[HA774 trade name]\* Sulfamethoxazole /trimethoprim 400 mg/80 mg tablets

Sulfamethoxazole/trimethoprim

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

Each uncoated tablet contains 400 mg sulfamethoxazole and 80 mg trimethoprim.

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

Contains lactose

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

100 uncoated 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**

Store at or below 30°C. Keep the bottle HDPE bottle pack tightly closed to protect from moisture.

### **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**

Shouguang Fukang Pharmaceutical Company Limited  
No. 666 Donghuan Road  
Shouguang City  
Shandong 262700  
China

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

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

HA774

**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**

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

Blister carton label

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

[HA774 trade name]<sup>†</sup> Sulfamethoxazole /trimethoprim 400 mg/80 mg tablets  
Sulfamethoxazole/trimethoprim

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

Each uncoated tablet contains 400 mg sulfamethoxazole and 80 mg trimethoprim.

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

Contains lactose

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

25 x 10 uncoated 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**

Store at or below 30°C. Store tablets in the blisters in the provided carton to protect from moisture and 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**

Shouguang Fukang Pharmaceutical Company Limited  
No. 666 Donghuan Road  
Shouguang City  
Shandong 262700  
China

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

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

HA774

**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

PVC/Aluminium blisters

**1. Name of the medicinal product**

[HA774 trade name] Sulfamethoxazole/trimethoprim 400 mg/80 mg tablets

Sulfamethoxazole/trimethoprim

**2. Name of the supplier**

Shouguang Fukang Pharmaceutical Company Limited

**3. Expiry date**

**4. Manufacturer's batch number**

<Batch> <Lot>{number}

**5. Other**