

## **LABELLING**

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

HDPE Bottle

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

[HA744 trade name]\* Sulfamethoxazole-trimethoprim 400 mg/80 mg tablets  
Sulfamethoxazole-trimethoprim

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

Each tablet contains sulfamethoxazole 400 mg and trimethoprim 80 mg.

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

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

100 tablets  
500 tablets  
1000 tablets

### **5. Method and route of administration**

Oral use.  
Do not chew.  
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. Avoid excursions above 30°C.

### **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**

Ipca Laboratories Limited  
48, Kandivli Industrial Estate  
Kandivli (W), Mumbai 400067  
India.

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

HA744

**13. Manufacturer's batch number**

<Batch> {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**

Carton blister label

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

[HA744 trade name] Sulfamethoxazole-trimethoprim 400 mg/80 mg tablets  
Sulfamethoxazole-trimethoprim

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

Each tablet contains sulfamethoxazole 400 mg and trimethoprim 80 mg.

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

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

Tablets  
10×10 tablets

### **5. Method and route of administration**

Oral use.  
Do not chew.  
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. Avoid excursions above 30°C.

### **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**

Ipca Laboratories Limited  
48, Kandivli Industrial Estate  
Kandivli (W), Mumbai 400067  
India.

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

HA744

**13. Manufacturer's batch number**

<Batch> {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**

PVdC/PVC-Aluminium Blister label

**1. Name of the medicinal product**

[HA744 trade name] Sulfamethoxazole-trimethoprim 400 mg/80 mg tablets

Sulfamethoxazole/trimethoprim

**2. Name of the supplier**

Ipca Laboratories Ltd

**3. Expiry date**

EXP {MM/YYYY}

**4. Manufacturer's batch number**

<Batch>-{number}

**5. Other**