

## **LABELLING**

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

HDPE bottle

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

[HA735 trade name]\* Sulfamethoxazole/ trimethoprim 400 mg/80 mg tablets  
sulfamethoxazole/trimethoprim

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

Each tablet contains 400 mg sulfamethoxazole and 80 mg trimethoprim

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

Each tablet contains 0.3 mg sodium benzoate  
See patient information leaflet for further information

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

500 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. Store in a dry place protected from light. Avoid exposure to temperatures 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**

Macleods Pharmaceuticals Limited  
Block N2, Village Theda  
P.O. Lodhimajra  
Tehsil Baddi, Dist. Solan  
Himachal Pradesh, 174 101  
India

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

HA735

**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 pack (PVC/PVdC-Aluminium)

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

[HA735 trade name]<sup>†</sup> sulfamethoxazole/trimethoprim 400 mg/80 mg tablets  
sulfamethoxazole/trimethoprim

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

Each tablet contains 400 mg sulfamethoxazole and 80 mg trimethoprim

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

Each tablet contains 0.3 mg sodium benzoate  
See patient information leaflet for further information

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

10 × 7 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. Store in a dry place protected from light. Avoid exposure to temperatures above 30°C  
Store the tablets in the blisters in the carton.

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<sup>†</sup> 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**

Macleods Pharmaceuticals Limited  
Block N2, Village Theda  
P.O. Lodhimajra  
Tehsil Baddi, Dist. Solan  
Himachal Pradesh, 174 101  
India

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

HA735

**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**

Blister

**1. Name of the medicinal product**

[HA735 trade name] Sulfamethoxazole/ trimethoprim 400 mg/80 mg tablets  
sulfamethoxazole/trimethoprim

**2. Name of the supplier**

Macleods Pharmaceuticals Limited

**3. Expiry date**

EXP {MM/YYYY}

**4. Manufacturer's batch number**

Batch {number}

**5. Other**