

Ethambutol hydrochloride/  
isoniazid/pyrazinamide/rifampicin  
275mg/75mg/400mg/150mg tablets  
(Micro Labs Ltd), TB223

WHOPAR Part 5

April 2023

## **LABELLING**

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

HDPE bottle

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

[TB223 trade name] \* Ethambutol hydrochloride/ isoniazid/pyrazinamide/rifampicin  
275mg/75mg/400mg/150mg tablets

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

Each tablet contains 150 mg rifampicin, 75 mg isoniazid, 400 mg pyrazinamide and 275 mg ethambutol hydrochloride

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

The tablets also carmoisine lake.  
See patient information leaflet for further information.

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

Film-coated tablets  
500 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}

Discard any remaining content of the HDPE bottle pack 30 days after first opening of the container.

Date of opening: DD / MM / YY

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

Do not store above 25°C. Store in a dry place and 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**

Micro Labs Limited  
# 31, Race Course Road  
Bangalore – 560001  
Karnataka, India

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

TB223

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

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**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**

Strip pack carton

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

[TB223 trade name] Ethambutol hydrochloride/ isoniazid/pyrazinamide/rifampicin  
275mg/75mg/400mg/150mg tablets

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

Each tablet contains 150 mg rifampicin, 75 mg isoniazid, 400 mg pyrazinamide and 275 mg ethambutol hydrochloride

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

The tablets also carmoisine lake.  
See patient information leaflet for further information.

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

Film-coated tablets

10 x 10 tablets  
24 x 28 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 25°C. Store in a dry place and 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**

Micro Labs Limited  
# 31, Race Course Road  
Bangalore – 560001  
Karnataka, India

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

TB223

### **13. Manufacturer's batch number**

<Batch> <Lot> {number}

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**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/Alu blister strips

**1. Name of the medicinal product**

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275mg/75mg/400mg/150mg tablets

**2. Name of the supplier**

Micro Labs Ltd

**3. Expiry date**

EXP {MM/YYYY}

**4. Manufacturer's batch number**

<Batch> <Lot>{number}

**5. Other**