

## **LABELLING**

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

HDPE bottle

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

[TB174 trade name] \* Isoniazid 300 mg tablets

Isoniazid

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

Each tablet contains 300 mg isoniazid.

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

Contains lactose and hydrogenated castor oil. See patient information leaflet for further information.

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

1000 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 30°C. Keep in a well-closed container, protected 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 560 001

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

Karnataka

India

Tel: 0091-80-22370451-54

Fax: 00-91-80 – 22370463

Email: exp@microlabs.in

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

TB174

**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**

Blister carton

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

[TB174 trade name] † Isoniazid 300 mg tablets

Isoniazid

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

Each tablet contains 300 mg isoniazid.

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

Contains lactose and hydrogenated castor oil. See patient information leaflet for further information.

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

10 x 10 tablets

28 x 24 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 30°C. Keep in a well-closed container, protected 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**

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

TB174

**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 strips (Alu/PVC/EVOH /Aclar or Alu/PVC/PVDC or Alu/PVC/PE/PVDC)

**1. Name of the medicinal product**

[TB174 trade name] Isoniazid 300 mg tablets

Isoniazid

**2. Name of the supplier**

Micro Labs Limited

**3. Expiry date**

EXP {MM/YYYY}

**4. Manufacturer's batch number**

Batch {number}

**5. Other**