

## **LABELLING**

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

### **Bottle HDPE**

**1. Name of the medicinal product**

[TB173 trade name]\*

Isoniazid 100 mg tablets

**2. Statement of active substance**

Each tablet contains 100 mg isoniazid.

**3. List of excipients**

Contains lactose monohydrate and hydrogenated castor oil.

See the patient information leaflet for further information.

**4. Pharmaceutical form and contents**

Uncoated tablets

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

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

Bangalore 560 001

Karnataka

India

Tel: 0091-80-22370451-54

Email: [info@microlabs.in](mailto:info@microlabs.in)

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

TB173

**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**

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

[TB173 trade name]<sup>†</sup>

Isoniazid 100 mg tablets

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

Each tablet contains 100 mg isoniazid.

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

Contains lactose monohydrate and hydrogenated castor oil.

See the patient information leaflet for further information.

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

Uncoated tablets

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, protect from light. Store tablets in blisters in the provided carton.

#### **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

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

TB173

**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 OR STRIP**

Alu-PVC/EVOH/Aclar blister

**1. Name of the medicinal product**

[TB173 trade name]

Isoniazid 100 mg tablets

**2. Name of the supplier**

Micro Labs Limited

**3. Expiry date**

EXP {MM/YYYY}

**4. Manufacturer's batch number**

<Batch> <Lot>{number}

**5. Other**