

## **LABELLING**

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

Bottle label/HDPE bottle

(with and without desiccant)

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

[TB285 trade name]<sup>1</sup>

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

Each tablet contains 300 mg isoniazid.

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

See patient information leaflet for further information.

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

30 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. Store in the original container. Protect from light.

### **10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate**

---

<sup>1</sup> Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

**11. Name and address of the supplier**

Mylan Laboratories Limited  
Plot No. 564/A/22  
Road No. 92, Jubilee Hills  
Hyderabad – 500 096, Telangana  
India

Email: [ProductSafety@viatris.com](mailto:ProductSafety@viatris.com)

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

TB285

**13. Manufacturer's batch number**

<Batch> {number}

**14. (Advice on) General classification for supply**

Medicinal product subject to medical prescription.

**15. Instructions on use**