

## **LABELLING**

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

Carton

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

[TB375 trade name]\* Isoniazid 300mg tablets  
Isoniazid

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

Each tablet contains Isoniazid 300 mg

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

See patient information leaflet

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

Uncoated tablets

1 x 10's

24 x 28's

### **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**

Store at a temperature below 30°C. Protected from light and moisture

### **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**

Lupin Limited  
Kalpataru Inspire  
3rd Floor, Off Western Express Highway  
Santacruz (East)  
Mumbai 400055  
India

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

TB375

**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**

Amber PVC/PVDC-Alu blister

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Isoniazid

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Santacruz (East)  
Mumbai 400055  
India

**3. Expiry date**

EXP {MM/YYYY}

**4. Manufacturer's batch number**

<Batch> <Lot>{number}

**5. Other**