

## **LABELLING**

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

Carton label

**1. Name of the medicinal product**

[TB347 trade name]\* isoniazid 50 mg dispersible tablets  
Isoniazid

**2. Statement of active substance**

Each tablet contains isoniazid 50 mg

**3. List of excipients**

Contains aspartame

**4. Pharmaceutical form and contents**

Dispersible tablet  
10 x 10 dispersible tablets  
24 x 28 dispersible 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 moisture and 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  
Bengaluru 560 001  
Karnataka  
India.

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

TB347

**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 STRIP

Aluminium strip

**1. Name of the medicinal product**

[TB347 trade name]\* isoniazid 50 mg dispersible tablets

Isoniazid

**2. Name of the supplier**

Micro Labs Limited

**3. Expiry date**

EXP {MM/YYYY}

**4. Manufacturer's batch number**

<Batch> <Lot> {number}

**5. Other**

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