

## **LABELLING**

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

Carton label

**1. Name of the medicinal product**

[TB359 trade name]\* Isoniazid 100 mg dispersible tablets

Isoniazid

**2. Statement of active substance**

Each tablet contains isoniazid 100 mg

**3. List of excipients**

**4. Pharmaceutical form and contents**

Dispersible tablet

10 x 10 tablets

20 x 10 tablets

3 x 28 tablets

24 x 28 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 dry condition, protect from light.

**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**

Macleods Pharmaceuticals Limited  
304, Atlanta Arcade  
Marol Church Road  
Andheri (East)  
Mumbai – 400 059  
India

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

TB359

**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

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Isoniazid

**2. Name of the supplier**

Macleods Pharmaceuticals Limited

**3. Expiry date**

**4. Manufacturer's batch number**

<Batch> <Lot> {number}

**5. Other**