

## **LABELLING**

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

Carton

**1. Name of the medicinal product**

[TB405 trade name]\* Isoniazid 100 mg dispersible tablets  
Isoniazid

**2. Statement of active substance**

Each tablet contains 100 mg isoniazid

**3. List of excipients**

Aspartame

**4. Pharmaceutical form and contents**

Dispersible tablet  
10 x 10 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.

**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**

S Kant Healthcare Limited  
3-A, Shiv Sagar Estate  
North Wing

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

Dr. Annie Besant Road  
Worli, Mumbai 400 018  
India

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

TB405

**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 foil

**1. Name of the medicinal product**

[TB405 trade name] Isoniazid 100 mg dispersible tablets

Isoniazid

**2. Name of the supplier**

S Kant Healthcare Limited

**3. Expiry date**

EXP {MM/YYYY}

**4. Manufacturer's batch number**

<Batch> <Lot>{number}

**5. Other**