

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Blister/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

1x10's

24x28'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

* 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> <Lot> {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

1. Name of the medicinal product

[TB375 trade name] Isoniazid 300mg tablets

Isoniazid 300mg tablets

2. Name of the supplier

Lupin Limited

Kalpataru Inspire

3rd Floor, Off Western Express Highway

Santacruz (East)

Mumbai 400055

India

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other