

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[TB360 trade name]*

Isoniazid/Rifampicin tablets

2. Statement of active substance

Each tablet contains Isoniazid 50 mg and Rifampicin 75 mg

3. List of excipients

Each tablet contains about 0.15mg of colour ponceau 4R (cochineal red A) and 2mg of aspartame
See patient information leaflet for further information

4. Pharmaceutical form and contents

Dispersible Tablets

1 x 10's strip pack

1 x 5's blister pack

14 x 6's strip pack

3 x 28's blister pack

3 x 28's strip pack

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

Store below 30°C. Store in a dry place protected from moisture. Avoid excursions above 30°C.

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

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

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

12. WHO Reference Number (Prequalification Programme)

TB360

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

Read patient information leaflet before use

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIP

Blisters

1. Name of the medicinal product

[TB360 trade name]
Isoniazid/Rifampicin 50mg/75mg tablets

2. Name of the supplier

Lupin Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

Batch {number}

5. Other