

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer carton

1. Name of the medicinal product

[TB196 trade name]* Isoniazid 100 g tablets

Isoniazid

2. Statement of active substance

Each tablet contains 100 mg isoniazid

3. List of excipients

4. Pharmaceutical form and contents

Tablet

100 (10 × 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. Keep in a well-closed container, protected from 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

Lupin Limited
Kalpataru Inspire

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

3rd Floor, Off Western Express Highway
Santacruz (East)
Mumbai 400055,
India
Tel: +91-22-66402370, 66402372
E-mail: globaltb@lupin.com

12. WHO Reference Number (Prequalification Programme)

TB196

13. Manufacturer's batch number

<Batch>{number}

14. (Advice on) General classification for supply

Medicinal product subject to medical prescription.

15. Instructions on use

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE Bottle

1. Name of the medicinal product

[TB196 trade name] Isoniazid 100 g tablets

Isoniazid

2. Statement of active substance

Each tablet contains 100 mg isoniazid

3. List of excipients

4. Pharmaceutical form and contents

Uncoated tablet.

100 tablets

1000 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. Keep in a well-closed container, protected from 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

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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

PVC/PVDC- aluminium blisters

1. Name of the medicinal product

[TB196 trade name] Isoniazid 100 mg tablets

Isoniazid

2. Name of the supplier

Lupin Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch>{number}

5. Other