

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Bottle label/HDPE bottle

(with and without desiccant)

1. Name of the medicinal product

[TB285 trade name]* Isoniazid 300 mg Tablets

Isoniazid

2. Statement of active substance

Each tablet contains 300 mg isoniazid

3. List of excipients

See patient information leaflet for further information.

4. Pharmaceutical form and contents

30 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. Store in the original package. Protect from light

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

Mylan Laboratories Limited
Plot No. 564/A/22
Road No. 92, Jubilee Hills
Hyderabad – 500 096, Telangana
India

Email: ProductSafety@viatris.com

12. WHO Reference Number (Prequalification Programme)

TB285

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

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Blister pack

1. Name of the medicinal product

[TB285 trade name][†] Isoniazid 300 mg Tablets

Isoniazid

2. Statement of active substance

Each tablet contains 300 mg isoniazid

3. List of excipients

See patient information leaflet for further information.

4. Pharmaceutical form and contents

10×10 tablets

24×28 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 the original package. Protect 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

Mylan Laboratories Limited
Plot No. 564/A/22

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Road No. 92, Jubilee Hills
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12. WHO Reference Number (Prequalification Programme)

TB285

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

Blister

1. Name of the medicinal product

[TB285 trade name] Isoniazid 300 mg Tablets
Isoniazid

2. Name of the supplier

Mylan Laboratories Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other