

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE Bottle

1. Name of the medicinal product

[TB308 trade name]* Isoniazid 100 mg tablets

Isoniazid

2. Statement of active substance

Each tablet contains 100 mg isoniazid

3. List of excipients

Each tablet contains mannitol.

See patient information leaflet for further information.

4. Pharmaceutical form and contents

100 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

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

Plot No.564/A/22

Road No. 92, Jubilee Hills

Hyderabad – 500096, Telangana India

Email: ProductSafety@viatris.com

12. WHO Reference Number (Prequalification Programme)

TB308

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

Blister carton

1. Name of the medicinal product

[TB308 trade name][†] Isoniazid 100 mg tablets

Isoniazid

2. Statement of active substance

Each tablet contains 100 mg isoniazid

3. List of excipients

Each tablet contains mannitol.

See patient information leaflet for further information.

4. Pharmaceutical form and contents

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. 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

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12. WHO Reference Number (Prequalification Programme)

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<Batch>{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 strips

1. Name of the medicinal product

[TB308 trade name] Isoniazid 100 mg tablets

Isoniazid

2. Name of the supplier

Mylan Laboratories Ltd.

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

BN {number}

5. Other