

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Bottle label/HDPE bottle

1. Name of the medicinal product

[TB276 trade name]* tablets

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

Tablets

500 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. Protect from light, in tightly closed container.

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

Cadila Pharmaceuticals Limited
1389, Dholka – 382225
District: Ahmedabad
Gujarat State, INDIA
Phone: ++91 2714-221481- 83

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

Fax: ++91 2714 220315

12. WHO Reference Number (Prequalification Programme)

TB276

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

Carton label/Blisters

1. Name of the medicinal product

[TB276 trade name][†] tablets

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

10x10 tablets

24x28 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. Protect from light, in tightly closed container.

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

Cadila Pharmaceuticals Limited
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Fax: ++91 2714 220315

12. WHO Reference Number (Prequalification Programme)

TB276

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

- 1. Name of the medicinal product**
[TB276 trade name] Isoniazid 300mg tablets
- 2. Name of the supplier**
Cadila Pharmaceuticals Limited
- 3. Expiry date**
EXP {MM/YYYY}
- 4. Manufacturer's batch number**
<Batch> <Lot>{number}
- 5. Other**