

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton/HDPE bottle label (White bottle with desiccant)

1. Name of the medicinal product

[TB392 trade name]*

Isoniazid 300 mg tablets

2. Statement of active substance

Each tablet contains isoniazid 300 mg.

3. List of excipients

See patient information leaflet for further information.

4. Pharmaceutical form and contents

1000 tablets.

5. Method and route of administration

Oral use.

Do not chew.

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 and avoid excursion above 30°C.

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

Svizera Labs Pvt. Ltd.
Plot no. D16/6, TTC Industrial Area,
MIDC, Turbhe,
Navi Mumbai 400703,
India

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

12. WHO Reference Number (Prequalification Programme)

TB392

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/blister (Alu-PVC/PVDC)

1. Name of the medicinal product

[TB392 trade name][†]

Isoniazid 300 mg tablets

2. Statement of active substance

Each tablet contains isoniazid 300 mg.

3. List of excipients

See patient information leaflet for further information.

4. Pharmaceutical form and contents

24 × 28 tablets

5. Method and route of administration

Oral use.

Do not chew.

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 and avoid excursion above 30°C.

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

Svizera Labs Pvt. Ltd.

Plot no. D16/6, TTC Industrial Area,

MIDC, Turbhe,

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

Navi Mumbai 400703,
India

12. WHO Reference Number (Prequalification Programme)

TB392

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

Alu-PVC/PVDC blister

1. Name of the medicinal product

[TB392]

Isoniazid 300 mg tablets

2. Name of the supplier

Svizera Labs Pvt Ltd

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch><Lot>{number}

5. Other