

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE container

1. Name of the medicinal product

[TB178 trade name]
Isoniazid 100 mg tablets.

2. Statement of active substance

Each tablet contains 100 mg isoniazid.

3. List of excipients

4. Pharmaceutical form and contents

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 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

Macleods Pharmaceuticals Limited
304, Atlanta Arcade
Marol Church road
Andheri (East)

Mumbai – 400 059, India.
Tel.: +91-22-66762800
Fax: +91-22-2821 6599
E-mail: exports@macleodspharma.com
vijay@macleodspharma.com
sjadhav@macleodspharma.com

12. WHO Reference Number (Prequalification Programme)

TB178

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

Carton

1. Name of the medicinal product

[TB178 trade name]

Isoniazid 100 mg tablets.

2. Statement of active substance

Each tablet contains 100 mg isoniazid.

3. List of excipients

4. Pharmaceutical form and contents

Tablets

10 × 3 tablets

10 × 10 tablets

28 × 3 tablets

28 × 24 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 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

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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

Al/PVC/PVdC blister and Alu-Alu strip

1. Name of the medicinal product

[TB178 trade name]

Isoniazid Tablets 100 mg

2. Name of the supplier

Macleods Pharmaceuticals Ltd.

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> {number}

5. Other