

LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

HDPE bottle

1. Name of the medicinal product

[TB179 trade name]* Isoniazid 300 mg tablets

Isoniazid

2. Statement of active substance

Each tablet contains isoniazid 300 mg

3. List of excipients

4. Pharmaceutical form and contents

Tablet

1000 tablets

30 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

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

India

12. WHO Reference Number (Prequalification Programme)

TB179

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 (Alu-PVC/PVDC blister) or (Aluminium foil strip)

1. Name of the medicinal product

[TB179 trade name][†] Isoniazid 300 mg tablets

Isoniazid

2. Statement of active substance

Each tablet contains isoniazid 300 mg

3. List of excipients

4. Pharmaceutical form and contents

Tablet

3 x 10 tablets

9 x 10 tablets

10 x 10 tablets

3 x 28 tablets

24 x 28 tablets

6 x 7 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

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304, Atlanta Arcade
Marol Church Road, Andheri (East)
Mumbai – 400 059
India

12. WHO Reference Number (Prequalification Programme)

TB179

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 or Aluminium foil strip

1. Name of the medicinal product

[TB179 trade name] Isoniazid 300 mg tablets

Isoniazid

2. Name of the supplier

Macleods Pharmaceuticals Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other