

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE bottle

1. Name of the medicinal product

[TB179 trade name]*

Isoniazid 300 mg tablets

2. Statement of active substance

Each tablet contains 300 mg isoniazid

3. List of excipients

4. Pharmaceutical form and contents

Tablets

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

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

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 6676 2800
Fax: +91 22 2821 6599
e-mail: vijay@macleodspharma.com or sjadhav@macleodspharma.com

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

Outer carton (blisters: Alu-PVDC/PVC) or (strips: Alu-Alu))

1. Name of the medicinal product

[TB179 trade name]*

Isoniazid 300 mg tablet

2. Statement of active substance

Each tablet contains 300 mg isoniazid

3. List of excipients

4. Pharmaceutical form and contents

Tablets

30 (10x3) tablets

90 (10x9) tablets

100 (10x10) tablets

84 (28x3) tablets

672 (28x24) tablets

42 (7x6) 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

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12. WHO Reference Number (Prequalification Programme)

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<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

Blisters: Alu-PVDC/PVC or strips: Alu-Alu

1. Name of the medicinal product

[TB179 trade name]

Isoniazid 300 mg tablets

2. Name of the supplier

Macleods Pharmaceuticals Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> {number}

5. Other