

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton label

1. Name of the medicinal product

[TB359 trade name]*

Isoniazid 100 mg dispersible tablets

2. Statement of active substance

Each tablet contains Isoniazid 100 mg

3. List of excipients

See patient information leaflet for further information.

4. Pharmaceutical form and contents

Dispersible tablets

10 × 10 tablets

20 × 10 tablets

24 × 28 tablets

3 × 28 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

Store below 30°C in a dry place, protect from light

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.

12. WHO Reference Number (Prequalification Programme)

TB359

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

Aluminium strip pack

1. Name of the medicinal product

[TB359 trade name] Isoniazid 100mg dispersible tablets

Isoniazid

2. Name of the supplier

Macleods Pharmaceuticals Limited
304, Atlanta Arcade
Marol Church road
Andheri (East)
Mumbai – 400 059, India.

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other