

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton label

1. Name of the medicinal product

[TB348 trade name]* Isoniazid 100 mg dispersible tablets
Isoniazid

2. Statement of active substance

Each tablet contains isoniazid 100 mg

3. List of excipients

Contains aspartame

4. Pharmaceutical form and contents

Dispersible tablet

10 x 10 tablets

24 x 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

Do not store above 30°C. Protect from moisture and 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

Micro Labs Limited

31, Race Course Road

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

Bengaluru
Karnataka, 560001
India

12. WHO Reference Number (Prequalification Programme)

TB348

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 STRIP

Aluminium strip

1. Name of the medicinal product

[TB348 trade name] Isoniazid 100 mg dispersible tablets

Isoniazid

2. Name of the supplier

Micro Labs Limited

3. Expiry date

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other