

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[TB369 trade name]*

Isoniazid/rifapentine 300 mg/300 mg film-coated tablets

2. Statement of active substance

Each film-coated tablet contains 300 mg isoniazid and 300 mg rifapentine.

3. List of excipients

See the patient information leaflet for further information.

4. Pharmaceutical form and contents

Film-coated tablet.

7 x 6 tablets

3 x 12 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 excessive heat and humidity.

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

12. WHO Reference Number (Prequalification Programme)

TB369

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/Alu strip

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2. Name of the supplier

Macleods Pharmaceuticals Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot> {number}

5. Other