

LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

HDPE bottle

1. Name of the medicinal product

[TB309 trade name]* Isoniazid/pyrazinamide/rifampicin 50 mg/150 mg/75 mg dispersible tablets

Isoniazid/pyrazinamide/rifampicin

2. Statement of active substance

Each tablet contains 50 mg isoniazid, 150 mg pyrazinamide and 75 mg rifampicin

3. List of excipients

Contains aspartame

4. Pharmaceutical form and contents

Dispersible tablets

100 dispersible 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 25°C. Store in a dry place. Protect from light.

Once the bottle is opened, use within 120 days.

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

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

Andheri (East)
Mumbai – 400 059
India

12. WHO Reference Number (Prequalification Programme)

TB309

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

Strip carton

1. Name of the medicinal product

[TB309 trade name][†] Isoniazid/pyrazinamide/rifampicin 50 mg/150 mg/75 mg dispersible tablets
Isoniazid/pyrazinamide/rifampicin

2. Statement of active substance

Each tablet contains 50 mg isoniazid, 150 mg pyrazinamide and 75 mg rifampicin

3. List of excipients

Contains aspartame

4. Pharmaceutical form and contents

Dispersible tablets

10 x 10 dispersible tablets

3 x 28 dispersible 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 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

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Mumbai – 400 059
India

12. WHO Reference Number (Prequalification Programme)

TB309

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/aluminium strip

1. Name of the medicinal product

[TB309 trade name] Isoniazid/pyrazinamide/rifampicin 50 mg/150 mg/75 mg dispersible tablets

Isoniazid/pyrazinamide/rifampicin

2. Name of the supplier

Macleods Pharmaceuticals Limited

3. Expiry date

4. Manufacturer's batch number

<Batch> <Lot> {number}

5. Other