

LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

HDPE bottle

1. Name of the medicinal product

[TB302 trade name]* Isoniazid/rifampicin 50 mg/75 mg dispersible tablets
Isoniazid/rifampicin

2. Statement of active substance

Each dispersible tablet contains 50 mg isoniazid and 75 mg rifampicin

3. List of excipients

Contains aspartame

4. Pharmaceutical form and contents

Dispersible tablet
100 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 dry place. Protect from light.
Once 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

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

Marol Church Road
Andheri (East) – 400 059
Mumbai
India

12. WHO Reference Number (Prequalification Programme)

TB302

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

Carton label

1. Name of the medicinal product

[TB302 trade name][†] Isoniazid/rifampicin 50 mg/75 mg dispersible tablets
Isoniazid/rifampicin

2. Statement of active substance

Each dispersible tablet contains 50 mg isoniazid and 75 mg rifampicin

3. List of excipients

Contains aspartame

4. Pharmaceutical form and contents

Dispersible tablet

10 x 10 tablets

3 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. Store in 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

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Marol Church Road
Andheri (East) – 400 059
Mumbai
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12. WHO Reference Number (Prequalification Programme)

TB302

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

Alu/alu strip

1. Name of the medicinal product

[TB302 trade name] Isoniazid/rifampicin 50 mg/75 mg dispersible tablets
Isoniazid/rifampicin

2. Name of the supplier

Macleods Pharmaceuticals Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot> {number}

5. Other