

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Bottle

1. Name of the medicinal product

[TB302 trade name]* Isoniazid/Rifampicin 50mg/75mg Dispersible Tablets

2. Statement of active substance

Each tablet contains 50 mg isoniazid and 75 mg rifampicin.

3. List of excipients

Contains aspartame

See patient information leaflet for further information.

4. Pharmaceutical form and contents

Dispersible tablets

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}

Date opened {DD/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

Marol Church road

Andheri (East)

Mumbai - 400 059

India

12. WHO Reference Number (Prequalification Programme)

TB302

13. Manufacturer's batch number

<Batch> <Lot> {number}

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

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 pack carton

1. Name of the medicinal product

[TB302 trade name] Isoniazid/Rifampicin 50mg/75mg Dispersible Tablets

2. Statement of active substance

Each tablet contains 50 mg isoniazid and 75 mg rifampicin.

3. List of excipients

Contains aspartame

See patient information leaflet for further information.

4. Pharmaceutical form and contents

Dispersible tablets

10 x 10 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

Marol Church road

Andheri (East)

Mumbai - 400 059

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

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIP

Alu/Alu strip

1. Name of the medicinal product

[TB302 trade name] Isoniazid/Rifampicin 50mg/75mg Dispersible Tablets

2. Name of the supplier

Macleods Pharmaceuticals Limited

3. Expiry date

4. Manufacturer's batch number

<Batch> <Lot> {number}

5. Other

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Nature/type}

1. Name of the medicinal product and route(s) of administration

[<PQ number> trade name] {name} {strength} {pharmaceutical form}

{Active substance(s)}

{Route(s) of administration}

2. Method of administration

3. Expiry date

4. Manufacturer's batch number

<Batch> <Lot> {number}

5. Contents by weight, by volume, or by unit

6. Other