

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING
Bottle

- 1. Name of the medicinal product**
[TB231 trade name]* Isoniazid /Rifampicin 150mg/300mg Tablets
- 2. Statement of active substance**
Each tablet contains 300 mg rifampicin and 150 mg isoniazid.
- 3. List of excipients**
Contains colour lake Ponceau 4R (Cochineal Red A).
See patient information leaflet for further information.
- 4. Pharmaceutical form and contents**
Film-coated tablets
500 tablets
1000 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**
Store below 30°C in a dry place. Protect from light.
Discard 45 days after first opening.
Date of opening {DD/MM/YYYY}
- 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)**
TB231
- 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

Blister carton

1. Name of the medicinal product

[TB231 trade name] Isoniazid /Rifampicin 150mg/300mg Tablets

2. Statement of active substance

Each tablet contains 300 mg rifampicin and 150 mg isoniazid.

3. List of excipients

Contains colour lake Ponceau 4R (Cochineal Red A).
See patient information leaflet for further information.

4. Pharmaceutical form and contents

Film-coated tablets

3 x 28 tablets

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

Store below 25°C 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
Andheri (East), Mumbai – 400 059
India

12. WHO Reference Number (Prequalification Programme)

TB231

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

Blister

1. Name of the medicinal product

[TB231 trade name] Isoniazid /Rifampicin 150mg/300mg Tablets

2. Name of the supplier

Macleods Pharmaceuticals Limited

3. Expiry date

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other