

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer carton (Bottle/HDPE)

1. Name of the medicinal product

[TB158 trade name]¹ Rifampicin/Isoniazid 150 mg /75 mg Film-coated Tablets

2. Statement of active substance

Each tablet contains 150 mg rifampicin and 75 mg isoniazid

3. List of excipients

Contains Lake of Ponceau 4R. See patient information leaflet for further information

4. Pharmaceutical form and contents

Film-coated Tablets

500 film-coated tablets

1000 film-coated 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 in a dry place below 30°C and protect from light.

¹ Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

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 Ltd.
304, Atlanta Arcade,
Marol Church Road,
Andheri (East),
Mumbai-400 059,
India
Tel: +91 22 6676 2800
Fax: +91 22 2821 6599
e-mail: exports@macleodspharma.com
vijay@macleodspharma.com
sjadhav@macleodspharma.com

12. WHO Reference Number (Prequalification Programme)

TB158

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

Label (Bottle/HDPE)

1. Name of the medicinal product

[TB158 trade name] Rifampicin/Isoniazid 150 mg /75 mg Film-coated Tablets

2. Statement of active substance

Each tablet contains 150 mg rifampicin and 75 mg isoniazid

3. List of excipients

Contains Lake of Ponceau 4R. See patient information leaflet for further information

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Film-coated Tablets

500 film-coated tablets

1000 film-coated tablets

5. Method and route of administration

Oral use.

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7. Other special warning(s), if necessary

8. Expiry date

EXP {MM/YYYY}

9. Special storage conditions

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<Batch> <Lot> {number}

14. (Advice on) General classification for supply

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15. Instructions on use

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer carton: blister (Alu-PVdC/PVC)

1. Name of the medicinal product

[TB158 trade name] Rifampicin/Isoniazid 150 mg /75 mg Film-coated Tablets

2. Statement of active substance

Each tablet contains 150 mg rifampicin and 75 mg isoniazid

3. List of excipients

Contains Lake of Ponceau 4R. See patient information leaflet for further information

4. Pharmaceutical form and contents

Film-coated Tablets

84 (28 x 3) film-coated tablets

100 (10 x 10) film-coated tablets

672 (28 x 24) film-coated 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 in a dry place below 30°C and 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

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12. WHO Reference Number (Prequalification Programme)

TB158

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

Outer carton: blister (Alu-PVC/PE/PVdC)

1. Name of the medicinal product

[TB158 trade name] Rifampicin/Isoniazid 150 mg /75 mg Film-coated Tablets

2. Statement of active substance

Each tablet contains 150 mg rifampicin and 75 mg isoniazid

3. List of excipients

Contains Lake of Ponceau 4R. See patient information leaflet for further information

4. Pharmaceutical form and contents

Film-coated Tablets

70 (7x10) film-coated tablets

84 (28x3) film-coated tablets

100 (10x10) film-coated tablets

672 (28x24) film-coated tablets

336 (28X12) film-coated 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 in a dry place below 30°C and 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

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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

Outer carton: Strip (Alu-Alu)

1. Name of the medicinal product

[TB158 trade name] Rifampicin/Isoniazid 150 mg /75 mg Film-coated Tablets

2. Statement of active substance

Each tablet contains 150 mg rifampicin and 75 mg isoniazid

3. List of excipients

Contains Lake of Ponceau 4R. See patient information leaflet for further information

4. Pharmaceutical form and contents

Film-coated Tablets

100 (10x10) film-coated 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 in a dry place below 30°C and 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

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12. WHO Reference Number (Prequalification Programme)

TB158

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

1. Name of the medicinal product

[TB158 trade name] Rifampicin/Isoniazid 150 mg /75 mg Film-coated Tablets

2. Name of the supplier

Macleods Pharmaceuticals Ltd

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}