

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer carton for strip

1. Name of the medicinal product

[TB259 trade name]*Rifampicin 150mg capsules

Rifampicin

2. Statement of active substance

Each hard capsule contains 150mg Rifampicin.

3. List of excipients

Contains FD&C Yellow #6 / Sunset Yellow, carmoisine, Ponceau 4R, sodium methylparaben and sodium propylparaben

See patient information leaflet for further information.

4. Pharmaceutical form and contents

Hard capsule

10x10 hard capsules

100x1 hard capsules

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 at a temperature not exceeding 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

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

11. Name and address of the supplier

Macleods Pharmaceuticals Limited
304, Atlanta Arcade
Marol Church Road
Andheri (East)
Mumbai – 400 059, INDIA
Tel: +91 022 66 76 28 00
Fax: +91 022 2821 65 99
E-mail; exports@macleodspharma.com
vijay@macleodspharma.com
sjadhav@macleodspharma.com

12. WHO Reference Number (Prequalification Programme)

TB259

13. Manufacturer's batch number

<Batch>{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

[TB259 trade name] Rifampicin 150mg capsules

Rifampicin

2. Name of the supplier

Macleods Pharmaceuticals Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch>{number}

5. Other

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE bottle

1. Name of the medicinal product

[TB259 trade name]†Rifampicin 150mg capsules

Rifampicin

2. Statement of active substance

Each hard capsule contains 150mg Rifampicin.

3. List of excipients

Contains FD&C Yellow #6 / Sunset Yellow, carmoisine, Ponceau 4R, sodium methylparaben and sodium propylparaben

See patient information leaflet for further information.

4. Pharmaceutical form and contents

Hard capsule

10x10 hard capsules

100x1 hard capsules

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 at a temperature not exceeding 25°C, in a dry place. Protect from light.

Dispense in tight container.

† 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 Limited
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12. WHO Reference Number (Prequalification Programme)

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<Batch>{number}

14. (Advice on) General classification for supply

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15. Instructions on use