

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton (Blister)

1. Name of the medicinal product

[TB332 trade name]* Rifampicin 300 mg Capsules

Rifampicin

2. Statement of active substance

Each capsule contains 300 mg rifampicin

3. List of excipients

Contains carmoisine (azorubine), sodium methyl parahydroxybenzoate, sodium propyl parahydroxybenzoate, sunset yellow (FD&C yellow #6) and ponceau 4R (cochineal red A)

See the patient information leaflet for further information.

4. Pharmaceutical form and contents

10 x 10 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 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, protected from light.

Store capsules in blisters in the provided carton.

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

12. WHO Reference Number (Prequalification Programme)

TB332

13. Manufacturer's batch number

<Batch> {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 (Strip)

1. Name of the medicinal product

[TB332 trade name] Rifampicin 300 mg Capsules

Rifampicin

2. Statement of active substance

Each capsule contains 300 mg rifampicin

3. List of excipients

Contains carmoisine (azorubine), sodium methyl parahydroxybenzoate, sodium propyl parahydroxybenzoate, sunset yellow (FD&C yellow #6) and ponceau 4R (cochineal red A)

See the patient information leaflet for further information

4. Pharmaceutical form and contents

10 x 10 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 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, protected from light.

Store capsules in blisters in the provided carton.

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)

TB332

13. Manufacturer's batch number

<Batch> {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

HDPE container

1. Name of the medicinal product

[TB332 trade name] Rifampicin 300 mg Capsules

Rifampicin

2. Statement of active substance

Each capsule contains 300 mg rifampicin

3. List of excipients

Contains carmoisine (azorubine), sodium methyl parahydroxybenzoate, sodium propyl parahydroxybenzoate, sunset yellow (FD&C yellow #6) and ponceau 4R (cochineal red A)

See the patient information leaflet for further information

4. Pharmaceutical form and contents

100 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 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, protected from light.

Store capsules in blisters in the provided carton.

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)

TB332

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 BLISTERS OR STRIP
ALU/ALU (Strips) and PVC-ALU (Blister cards)

1. Name of the medicinal product

[TB332 trade name] Rifampicin 300 mg Capsules
Rifampicin

2. Name of the supplier

Macleods Pharmaceuticals Ltd

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other