

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Bottle carton and label

1. Name of the medicinal product

[TB168 trade name]* Rifampicin/Isoniazid/ Pyrazinamide/Ethambutol Hydrochloride 150 mg/ 75 mg/ 400 mg/275 mg film-coated Tablets

Rifampicin/Isoniazid/ Pyrazinamide/Ethambutol Hydrochloride

2. Statement of active substance

Each tablet contains 150 mg rifampicin, 75 mg isoniazid, 400 mg pyrazinamide and 275 mg ethambutol.

3. List of excipients

Contains lake of sunset yellow.

See patient information leaflet

4. Pharmaceutical form and contents

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 at a temperature not exceeding 25° C in a dry place and protect from light.

* 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
304, Atlanta Arcade,
Marol Church road,
Andheri (East),
Mumbai – 400 059, India

12. WHO Reference Number (Prequalification Programme)

TB168

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

Blister carton (*Alu/PVC/PVDC Blister packs*)

1. Name of the medicinal product

[TB168 trade name][†] Rifampicin/Isoniazid/ Pyrazinamide/Ethambutol Hydrochloride 150 mg/ 75 mg/ 400 mg/275 mg film-coated Tablets

Rifampicin/Isoniazid/ Pyrazinamide/Ethambutol Hydrochloride

2. Statement of active substance

Each tablet contains 150 mg rifampicin, 75 mg isoniazid, 400 mg pyrazinamide and 275 mg ethambutol.

3. List of excipients

Contains lake of sunset yellow.

See patient information leaflet

4. Pharmaceutical form and contents

10 x 10 film-coated tablets

10 x 7 film-coated tablets

28 x 3 film-coated tablets

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

Stored in a dry place below 25°C and protect from light.

[†] 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
304, Atlanta Arcade,
Marol Church road,
Andheri (East),
Mumbai – 400 059, India

12. WHO Reference Number (Prequalification Programme)

TB168

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

Blister carton (*Alu/PVC/PE/PVDC Blister packs*)

1. Name of the medicinal product

[TB168 trade name][‡] Rifampicin/Isoniazid/ Pyrazinamide/Ethambutol Hydrochloride 150 mg/ 75 mg/ 400 mg/275 mg film-coated Tablets

Rifampicin/Isoniazid/ Pyrazinamide/Ethambutol Hydrochloride

2. Statement of active substance

Each tablet contains 150 mg rifampicin, 75 mg isoniazid, 400 mg pyrazinamide and 275 mg ethambutol.

3. List of excipients

Contains lake of sunset yellow.

See patient information leaflet

4. Pharmaceutical form and contents

10 x 10 film-coated tablets

7 x 10 film-coated tablets

28 x 3 film-coated tablets

28 x 6 film-coated tablets

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

Stored in a dry place below 25°C and protect from light.

[‡] 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
304, Atlanta Arcade,
Marol Church road,
Andheri (East),
Mumbai – 400 059, India

12. WHO Reference Number (Prequalification Programme)

TB168

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

Blister carton (*Alu/Alu strips*)

1. Name of the medicinal product

[TB168 trade name][§] Rifampicin/Isoniazid/ Pyrazinamide/Ethambutol Hydrochloride 150 mg/ 75 mg/ 400 mg/275 mg film-coated Tablets

Rifampicin/Isoniazid/ Pyrazinamide/Ethambutol Hydrochloride

2. Statement of active substance

Each tablet contains 150 mg rifampicin, 75 mg isoniazid, 400 mg pyrazinamide and 275 mg ethambutol.

3. List of excipients

Contains lake of sunset yellow.

See patient information leaflet.

4. Pharmaceutical form and contents

10 x 10 film-coated tablets

12 x 14 film-coated tablets

28 x 3 film-coated tablets

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 out of the 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.

[§] 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
304, Atlanta Arcade,
Marol Church road,
Andheri (East),
Mumbai – 400 059, India

12. WHO Reference Number (Prequalification Programme)

TB168

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 BLISTERS OR STRIP

Blister strip

1. Name of the medicinal product

[TB168 trade name]** Rifampicin/Isoniazid/ Pyrazinamide/Ethambutol Hydrochloride 150 mg/ 75 mg/ 400 mg/275 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}

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