

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING
BOTTLE LABEL (HDPE)**

1. Name of the medicinal product

[TB068 trade name]* Rifampicin/Isoniazid 150 mg/75 mg tablets
Rifampicin/Isoniazid

2. Statement of active substance

Each tablet contains 150 mg rifampicin and 75 mg isoniazid

3. List of excipients

See patient information leaflet for further information.

4. Pharmaceutical form and contents

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 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, protected from excessive humidity. 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

Lupin Limited
Kalpataru Inspire
3rd Floor, Off Western Express Highway

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

Santacruz (East)
Mumbai 400055
India

12. WHO Reference Number (Prequalification Programme)

TB068

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 label/Alu-PVC/PVDC blisters

1. Name of the medicinal product

[TB068 trade name] Rifampicin/Isoniazid 150 mg/75 mg tablets

Rifampicin/Isoniazid

2. Statement of active substance

Each tablet contains 150 mg rifampicin and 75 mg isoniazid

3. List of excipients

See patient information leaflet for further information.

4. Pharmaceutical form and contents

15 x 6 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 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, protected from excessive humidity. 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

Lupin Limited
Kalpataru Inspire
3rd Floor, Off Western Express Highway
Santacruz (East)

Mumbai 400055
India

12. WHO Reference Number (Prequalification Programme)

TB068

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 label/Cold form Alu-Alu blisters

1. Name of the medicinal product

[TB068 trade name] Rifampicin/Isoniazid 150 mg/75 mg tablets

Rifampicin/Isoniazid

2. Statement of active substance

Each tablet contains 150 mg rifampicin and 75 mg isoniazid

3. List of excipients

See patient information leaflet for further information.

4. Pharmaceutical form and contents

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 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, protected from excessive humidity. 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

Lupin Limited
Kalpataru Inspire
3rd Floor, Off Western Express Highway
Santacruz (East)
Mumbai 400055
India

12. WHO Reference Number (Prequalification Programme)

TB068

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 label/Alu-PVC/PE/PVDC blisters

16. Name of the medicinal product

[TB068 trade name] Rifampicin/Isoniazid 150 mg/75 mg tablets
Rifampicin/Isoniazid

17. Statement of active substance

Each tablet contains 150 mg rifampicin and 75 mg isoniazid

18. List of excipients

See patient information leaflet for further information.

19. Pharmaceutical form and contents

24 x 28 tablets

20. Method and route of administration

Oral use

Read the patient information leaflet before use.

21. 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.

22. Other special warning(s), if necessary

23. Expiry date

EXP {MM/YYYY}

24. Special storage conditions

Store below 25°C, protected from excessive humidity. Protect from light.

25. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate

26. Name and address of the supplier

Lupin Limited
Kalpataru Inspire
3rd Floor, Off Western Express Highway
Santacruz (East)
Mumbai 400055
India

27. WHO Reference Number (Prequalification Programme)

TB068

28. Manufacturer's batch number

<Batch> {number}

29. (Advice on) General classification for supply

Medicinal product subject to medical prescription.

30. Instructions on use

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIP

1. Name of the medicinal product

[TB068 trade name] Rifampicin/Isoniazid 150 mg/75 mg tablets
Rifampicin/Isoniazid

2. Name of the supplier

Lupin Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> {number}