

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Strip pack carton

1. Name of the medicinal product

[TB400 trade name]* Isoniazid/pyrazinamide/rifampicin 50 mg/150 mg/75 mg dispersible tablets
Isoniazid/pyrazinamide/rifampicin

2. Statement of active substance

Each tablet contains 50 mg isoniazid, 150 mg pyrazinamide and 75 mg rifampicin

3. List of excipients

Contains aspartame

4. Pharmaceutical form and contents

Dispersible tablets

10 x 6 dispersible tablets

3 x 28 dispersible 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 below 30°C. Protect from light and moisture.

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

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

Isoniazid/pyrazinamide/rifampicin
50 mg/150 mg/75 mg dispersible tablets
(Lupin Limited), TB400

WHOPAR Part 5

October 2024

3rd Floor, Off Western Express Highway
Santacruz (East)
Mumbai 400055
India

12. WHO Reference Number (Prequalification Programme)

TB400

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 STRIP

Aluminium foil strip

1. Name of the medicinal product

[TB400 trade name] Isoniazid/pyrazinamide/rifampicin 50 mg/150 mg/75 mg dispersible tablets

Isoniazid/pyrazinamide/rifampicin

2. Name of the supplier

Lupin Limited

3. Expiry date

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Blister pack carton

1. Name of the medicinal product

[TB400 trade name][†] Isoniazid/pyrazinamide/rifampicin 50 mg/150 mg/75 mg dispersible tablets
Isoniazid/pyrazinamide/rifampicin

2. Statement of active substance

Each tablet contains 50 mg isoniazid, 150 mg pyrazinamide and 75 mg rifampicin

3. List of excipients

Contains aspartame

4. Pharmaceutical form and contents

Dispersible tablets
10 x 10 dispersible 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 below 30°C. Protect from light and moisture.

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.
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Isoniazid/pyrazinamide/rifampicin
50 mg/150 mg/75 mg dispersible tablets
(Lupin Limited), TB400

WHOPAR Part 5

October 2024

Santacruz (East)

Mumbai 400055

India

12. WHO Reference Number (Prequalification Programme)

TB400

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

Alu/alu foil blister

1. Name of the medicinal product

[TB400 trade name] Isoniazid/pyrazinamide/rifampicin 50 mg/150 mg/75 mg dispersible tablets

Isoniazid/pyrazinamide/rifampicin

2. Name of supplier

Lupin Limited

3. Expiry date

4. Manufacturer's batch number

<Batch> <Lot> {number}

5. Other