

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product”

[TB402 trade name]* Rifapentine 150mg dispersible tablets
Rifapentine

2. Statement of active substance

Each dispersible tablet contains 150 mg rifapentine

3. List of excipients

Contains aspartame.

4. Pharmaceutical form and contents

Dispersible tablet

10 x 10 tablets

10 x 12 tablets

1 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 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 excessive heat and moisture.

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

Lupin Limited
Kalpataru Inspire
3rd Floor, Off Western Express Highway,
Santacruz (East), Mumbai
Maharashtra 400 055,
India

12. WHO Reference Number (Prequalification Programme)

TB402

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

Aluminium foil strip packs

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Rifapentine

2. Name of the supplier

Lupin Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> {number}

5. Other