

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[TB393 trade name]* Rifapentine 300 mg film-coated tablets
Rifapentine

2. Statement of active substance

Each film-coated tablet contains 300 mg of rifapentine.

3. List of excipients

Each tablet also contains about 0.15 mg of colourant FD&C yellow #6/sunset yellow FCF aluminium lake.
See patient information leaflet for further information.

4. Pharmaceutical form and contents

Film-coated tablets

10 x 10 tablets

3 x 12 tablets

2 x 14 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 and sight of children.

7. Other special warning(s), if necessary

8. Expiry date

EXP {MM/YYYY}

9. Special storage conditions

Do not store above 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

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)

TB393

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

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

Aluminium strips and blister packs

1. Name of the medicinal product

[TB393 trade name] Rifapentine 300 mg film-coated tablets
Rifapentine

2. Name of the supplier

Lupin Ltd.

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other