

## **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.

See the patient information leaflet for further information.

#### **4. Pharmaceutical form and contents**

Dispersible tablet

10 x 10

10 x 12

1 x 28

#### **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**

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

Rifapentine

**2. Name of the supplier**

Lupin Limited

**3. Expiry date**

EXP {MM/YYYY}

**4. Manufacturer's batch number**

<Batch> {number}

**5. Other**