

## **LABELLING**

## **PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

Carton

**1. Name of the medicinal product**

[TB398 trade name]\* Rifapentine 300 mg film coated tablets  
Rifapentine

**2. Statement of active substance**

Each film-coated tablet contains 300 mg rifapentine

**3. List of excipients**

See the patient information leaflet for further information.

**4. Pharmaceutical form and contents**

Film-coated tablets.  
10 x 10 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**

Do not store above 30°C. Protect from excessive heat and humidity. Avoid excursions above 30°C.

**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**

Macleods Pharmaceuticals Limited

304, Atlanta Arcade

Marol Church road

Andheri (East)

Mumbai – 400 059, India

Tel: +91-22-66762800

Fax: +91-22-28216599

**12. WHO Reference Number (Prequalification Programme)**

TB398

**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**

Alu/Alu strips

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[TB398 trade name] Rifapentine 300 mg film coated tablets

Rifapentine

**2. Name of the supplier**

Macleods Pharmaceuticals Limited

**3. Expiry date**

EXP {MM/YYYY}

**4. Manufacturer's batch number**

<Batch> {number}

**5. Other**