

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton of foil pack

1. Name of the medicinal product

[TB412 trade name]* Rifapentine 150 mg dispersible tablets
Rifapentine

2. Statement of active substance

Each dispersible tablet contains 150 mg rifapentine

3. List of excipients

Contains aspartame. See patient information leaflet for further information

4. Pharmaceutical form and contents

Dispersible tablets
10 × 12 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

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

Macleods Pharmaceuticals Limited
304, Atlanta Arcade

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

Marol Church road
Andheri (East)
Mumbai – 400 059, India.

12. WHO Reference Number (Prequalification Programme)

TB412

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 OR STRIP

Alu/Alu Strips

1. Name of the medicinal product

[TB412 trade name] Rifapentine 150mg dispersible tablets

Rifapentine

2. Name of the supplier

Macleods Pharmaceuticals Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other