

## **LABELING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

**Bottle label/HDPE**

**1. NAME OF THE MEDICINAL PRODUCT**

Rifampicin/Isoniazid 75 mg/50 mg Dispersible Tablets \*

**2. STATEMENT OF ACTIVE SUBSTANCE**

Each dispersible tablet contains 75 mg rifampicin and 50 mg isoniazid

**3. LIST OF EXCIPIENTS**

Contains aspartame  
See patient information leaflet for further information.

**4. PHARMACEUTICAL FORM AND CONTENTS**

100 dispersible 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}

\* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility. Throughout this WHOPAR the Proprietary Name is given as an example only.

**9. SPECIAL STORAGE CONDITIONS**

Do not store above 25°C, store in dry place, protect from light.  
Once opened use within 120 days

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

**12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)**

TB302

**13. MANUFACTURER'S BATCH NUMBER**

<Batch> {number}

**14. GENERAL CLASSIFICATION FOR SUPPLY**

Medicinal product subject to medical prescription.

**15. INSTRUCTIONS ON USE**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

**Carton label/Alu-Alu strips**

**1. NAME OF THE MEDICINAL PRODUCT**

Rifampicin/Isoniazid 75 mg/50 mg Dispersible Tablets †

**2. STATEMENT OF ACTIVE SUBSTANCE**

Each dispersible tablet contains 75 mg rifampicin and 50 mg isoniazid

**3. LIST OF EXCIPIENTS**

Contains aspartame  
See patient information leaflet for further information.

**4. PHARMACEUTICAL FORM AND CONTENTS**

10 x10 dispersible 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}

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**9. SPECIAL STORAGE CONDITIONS**

Do not store above 25°C, store in dry place, protect from light.

**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**

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**12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)**

TB302

**13. MANUFACTURER'S BATCH NUMBER**

<Batch> {number}

**14. GENERAL CLASSIFICATION FOR SUPPLY**

Medicinal product subject to medical prescription.

**15. INSTRUCTIONS ON USE**

**MINIMUM PARTICULARS TO APPEAR ON BLISTER**

**1. NAME OF THE MEDICINAL PRODUCT**

Rifampicin/Isoniazid 75 mg/50 mg Dispersible Tablets ‡

**2. NAME OF THE SUPPLIER**

Macleods Pharmaceuticals Limited

**3. EXPIRY DATE**

EXP {DD/MM/YYYY}

**4. BATCH NUMBER**

<Batch> {number}

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