

LABELLING

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND
THE IMMEDIATE PACKAGING**

HDPE bottle

1. NAME OF THE MEDICINAL PRODUCT

Rifampicin/Isoniazid/Pyrazinamide 75 mg/50 mg/150 mg Dispersible Tablets 1

2. STATEMENT OF ACTIVE SUBSTANCE

Each tablet contains 75 mg rifampicin, 50 mg isoniazid and 150 mg pyrazinamide

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 sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

¹ 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.

8. EXPIRY DATE

EXP {MM/YYYY}

9. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Store in a dry place. Protect from light.

Once opened, use within 120 days

Once dispersed in water, the mixture should be used within 10 minutes.

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)

TB309

13. MANUFACTURER'S BATCH NUMBER

BN {number}

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Strip Carton

1. NAME OF THE MEDICINAL PRODUCT

Rifampicin/Isoniazid/Pyrazinamide 75 mg /50 mg/150 mg Dispersible Tablets

2. STATEMENT OF ACTIVE SUBSTANCE

Each tablet contains 75 mg rifampicin, 50 mg isoniazid and 150 mg pyrazinamide

3. LIST OF EXCIPIENTS

Contains aspartame

See patient information leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

100 (10 x 10) dispersible tablets

84 (28 x 3) 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 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 25°C. Store in a dry place. Protect from light.

Once dispersed in water, the mixture should be used within 10 minutes.

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Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

MINIMUM PARTICULARS TO APPEAR ON STRIPS

1. NAME OF THE MEDICINAL PRODUCT

Rifampicin/Isoniazid/Pyrazinamide 75mg/50mg/150mg Dispersible Tablets

2. NAME OF THE SUPPLIER

Macleods Pharmaceuticals Limited

3. EXPIRY DATE

EXP {MM/YYYY}

4. BATCH NUMBER

BN {number}