

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Bottle label

1. NAME OF THE MEDICINAL PRODUCT

Isoniazid/Rifampicin 150 mg/150 mg Tablets *

2. STATEMENT OF ACTIVE SUBSTANCE

Each film-coated tablet contains 150 mg isoniazid, 150 mg rifampicin.

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

1000 film-coated 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}

9. SPECIAL STORAGE CONDITIONS

Store in a dry place below 25°C, protected from excessive humidity and light.

* 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.

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

Lupin Limited
Kalpataru Inspire
3rd Floor, Off Western Express Highway
Santacruz (East)
Mumbai 400055,
India
Tel : +91 22 66402323
E-mail: rajeevpatil@lupinpharma.com

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

TB195

13. MANUFACTURER'S BATCH NUMBER

<Batch><Lot><BN> {number}

14. (ADVICE ON) GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer carton label (Blister)

1. NAME OF THE MEDICINAL PRODUCT

Isoniazid/Rifampicin 150 mg/150 mg Tablets

2. STATEMENT OF ACTIVE SUBSTANCE

Each film-coated tablet contains 150 mg isoniazid, 150 mg rifampicin.

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

672 (28 × 24) film-coated 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}

9. SPECIAL STORAGE CONDITIONS

Store in a dry place below 25°C, protected from excessive humidity and 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

Lupin Limited
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TB195

13. MANUFACTURER'S BATCH NUMBER

<Batch><Lot><BN> {number}

14. (ADVICE ON) GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

Isoniazid/Rifampicin 150 mg/150 mg Tablets

1. NAME OF THE MEDICINAL PRODUCT

Isoniazid/Rifampicin 150 mg/150 mg Tablets

2. NAME OF THE SUPPLIER

Lupin Limited

3. EXPIRY DATE

EXP {MM/YYYY}

4. BATCH NUMBER

<Batch> <Lot> <BN> {number}