

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton (for blister)

1. NAME OF THE MEDICINAL PRODUCT

Rimactazid 150 mg/75 mg film-coated tablets

rifampicin/isoniazid

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each film-coated tablet contains 150 mg rifampicin and 75 mg isoniazid.

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

30 film-coated tablets
60 film-coated tablets
120 film-coated tablets
240 film-coated tablets
672 film-coated tablets
1,000 film-coated tablets

5. METHOD OF ADMINISTRATION AND ROUTE(S)

Read the package insert before use.
To be swallowed.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of reach and sight of children.

7. OTHER SPECIAL WARNINGS IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

“Do not store above 25°C. Store in the original package in order to protect from moisture”.

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 MARKETING AUTHORISATION HOLDER

Sandoz A/S, 2300 Copenhagen S, Denmark

12. MARKETING AUTHORISATION NUMBER(S)

16688

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Prescription medication.

15. INSTRUCTIONS FOR USE

16. INFORMATION IN BRAILLE

Rimactazid

17. UNIQUE IDENTIFIER - 2D BARCODE

2D barcode containing the unique identifier.

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC: {number}
SN: {number}
NN: {number}

PARTICULARS TO APPEAR ON OUTER PACKAGING AND INNER PACKAGING

Carton (for bottle), label (for bottle)

1. NAME OF THE MEDICINAL PRODUCT

Rimactazid 150 mg/75 mg film-coated tablets

rifampicin /isoniazid

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each film-coated tablet contains 150 mg rifampicin and 75 mg isoniazid.

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

500 film-coated tablets

5. METHOD OF ADMINISTRATION AND ROUTE(S)

Read the package insert before use.
To be swallowed.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of reach and sight of children.

7. OTHER SPECIAL WARNINGS IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Do not store above 30°C.
Close the bottle tightly. Sensitive to moisture.

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 MARKETING AUTHORISATION HOLDER

Sandoz A/S, 2300 Copenhagen S, Denmark

12. MARKETING AUTHORISATION NUMBER(S)

16688

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Prescription medication.

15. INSTRUCTIONS FOR USE

16. INFORMATION IN BRAILLE

Rimactazid
(for carton, for bottle)

17. UNIQUE IDENTIFIER - 2D BARCODE

For carton only:
2D barcode containing the unique identifier.

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

For carton only:
PC: {number}
SN: {number}
NN: {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

PVC/PE/PVDC-Alu Blister

1. NAME OF THE MEDICINAL PRODUCT

Rimactazid 150 mg/75 mg film-coated tablets

rifampicin /isoniazid

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Sandoz A/S

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. OTHER