

Isoniazid Atb 300 mg tablets
Isoniazid

PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING

OUTER CARTON

1. NAME OF THE MEDICINAL PRODUCT

Isoniazid Atb 300 mg tablets
Isoniazid

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains 300 mg of isoniazid.

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

Tablet
30 tablets
1500 tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package 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

Package of hospital use – package of 1500 tablets

8. EXPIRY DATE

EXP
Do not use after the expiry date printed on the package.

9. SPECIAL STORAGE CONDITIONS

Store below 25 °C, in the original package.

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

Antibiotice SA
1 Valea Lupului Street, 707410, Iasi, Romania, EU
Antibiotice logo

12. MARKETING AUTHORISATION NUMBER(S)

8968/2016/01 – 30 tablets
8968/2016/02 – 1500 tablets

13. BATCH NUMBER

Lot:

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription. – package of 30 tablets.

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Isoniazid Atb 300 mg (for the package of 30 tablets)

17. UNIQUE IDENTIFIER – 2D BARCODE

<2D barcode carrying the unique identifier included.>

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC:
SN:
NN:

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS
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Blister

1. NAME OF THE MEDICINAL PRODUCT

Isoniazid Atb 300 mg tablets
Isoniazid

2. NAME OF THE MARKETING AUTHORISATION HOLDER
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Antibiotice logo

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. OTHER INFORMATION
