

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

**OUTER CARTON**

**1. NAME OF THE MEDICINAL PRODUCT**

Sinerdol 300 mg hard capsules  
Rifampicin

**2. STATEMENT OF ACTIVE SUBSTANCE(S)**

Each hard capsule contains 300 mg of rifampicin.

**3. LIST OF EXCIPIENTS**

This medicine contains lactose monohydrate, Amaranth (E123), methyl parahydroxybenzoate (E 218), propyl parahydroxybenzoate (E216). See the leaflet for further information.

**4. PHARMACEUTICAL FORM AND CONTENTS**

Hard, Capsules  
10 hard capsules  
1000 hard capsules

**5. METHOD AND ROUTE(S) OF ADMINISTRATION**

Read the package leaflet before use.  
Oral 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 for hospital use – for the package of 1000 hard capsules.

**8. EXPIRY DATE**

EXP

**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, Iasi 707410, Romania

Antibiotice logo

**12. MARKETING AUTHORISATION NUMBER(S)**

9187/2016/01-02

**13. BATCH NUMBER**

Lot:

**14. GENERAL CLASSIFICATION FOR SUPPLY**

Medicinal product subject to medical prescription. (package of 10 hard capsules)

**15. INSTRUCTIONS ON USE**

**16. INFORMATION IN BRAILLE**

Sinerdol 300 mg

**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**

Blister

**1. NAME OF THE MEDICINAL PRODUCT**

Sinerdol 300 mg hard capsules  
Rifampicin

**2. NAME OF THE MARKETING AUTHORISATION HOLDER**

Antibiotice logo

**3. EXPIRY DATE**

EXP

**4. BATCH NUMBER**

Lot

**5. OTHER INFORMATION**