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

#### **OUTER CARTON**

### 1. NAME OF THE MEDICINAL PRODUCT

Sinerdol 150 mg hard capsules Rifampicin

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

Each hard capsule contains 150 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 20 hard capsules 1000 hard capsules

#### 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 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)
9186/2016/01-02
13. BATCH NUMBER
Lot:
14. GENERAL CLASSIFICATION FOR SUPPLY
Medicinal product subject to medical prescription. (package of 20 hard capsules)
15. INSTRUCTIONS ON USE
16. INFORMATION IN BRAILLE
Sinerdol 150 mg
17. UNIQUE IDENTIFIER – 2D BARCODE
<2D barcode carrying the unique identifier included.>
18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC: SN: NN:

5.

OTHER INFORMATION

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS
Blister
1. NAME OF THE MEDICINAL PRODUCT
1. NAME OF THE MEDICINAL I RODUCT
Sinerdol 150 mg hard capsules
Rifampicin
2. NAME OF THE MARKETING AUTHORISATION HOLDER
Antibiotice logo
3. EXPIRY DATE
EXP
4. BATCH NUMBER
Lot