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1.3.1 spc-label-pl - common-outer – 5,430 (NL/H/2965-2966/001-166280)		20191105
LINEZOLID 600 MG FILM-COATED TABLET		722-1479.00

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON FOR OPA/ALU/PVC/ALU BLISTER

1. NAME OF THE MEDICINAL PRODUCT

[nationally completed name] 600 mg film-coated tablets

linezolid

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each film-coated tablet contains 600 mg of linezolid.

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

NL/H/2965/001:

10 film-coated tablets
10 (10x1) film-coated tablets
20 film-coated tablets
28 film-coated tablets
30 film-coated tablets
50 film-coated tablets
60 film-coated tablets
100 film-coated tablets

NL/H/2966/001:

10 film-coated tablets
10 (10x1) film-coated tablets
30 film-coated tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

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Read the package leaflet before use.

Oral use.

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

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

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

[To be completed nationally]

12. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

13. BATCH NUMBER

Batch

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14. GENERAL CLASSIFICATION FOR SUPPLY

[To be completed nationally]

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

[To be completed nationally]

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC: {number}

SN: {number}

NN: {number}

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MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

OPA/ALU/PVC/ALU BLISTER

1. NAME OF THE MEDICINAL PRODUCT

[nationally completed name] 600 mg film-coated tablets

linezolid

2. NAME OF THE MARKETING AUTHORISATION HOLDER

[To be completed nationally]

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Batch

5. OTHER