EU LABELS – EU-LAB (LAB/EU/ENGLISH)

BERINERT

Rev.: **02-MAY-2017** / Switch to 1-Box Version

Supersedes previous versions
Rev.: 26-NOV-2014 / Name Change, response to questions
Rev.: 12-SEP-2014 / Name Change
Rev.: 30-Jul-2013 / Renewal and adaptation to QRD template

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

1. NAME OF THE MEDICINAL PRODUCT

Berinert 500
500 IU
Powder and solvent for solution for injection / infusion.

2. STATEMENT OF THE ACTIVE SUBSTANCE(S)

Berinert 500 contains the following active substance per vial:

C1-esterase inhibitor, human	500 IU
Total protein	65 mg

3. LIST OF EXCIPIENTS

Other ingredients per vial:
Glycine, *sodium chloride, *sodium citrate, water for injections

4. PHARMACEUTICAL FORM AND CONTENTS

Powder and solvent for solution for injection / infusion.
Box containing:
1 vial with powder (500 IU)
1 vial with 10 ml water for injections
1 filter transfer device 20/20 (Mix2Vial)
Administration set (inner box):
1 disposable 10 ml syringe
1 venipuncture set
2 alcohol swabs
1 non-sterile plaster

5. METHOD AND ROUTE(S) OF ADMINISTRATION

*Read the package leaflet before 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

- not applicable -

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Do not freeze.
Keep the vial in the outer carton.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

Any unused solution must be discarded appropriately.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

CSL Behring GmbH, 35041 Marburg, Germany

12. MARKETING AUTHORISATION NUMBER(S)

MA No.

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

- not applicable -

16. INFORMATION IN BRAILLE

Berinert 500

17. UNIQUE IDENTIFIER – 2D BARCODE

<2D barcode carrying the unique identifier included.>

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

<PC: {number} [product code]
SN: {number} [serial number]
NN: {number} [national reimbursement number or other national number identifying the medicinal product]>

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS (SUBSTANCE LABEL)

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Berinert 500
Powder for intravenous administration after reconstitution.

2. METHOD OF ADMINISTRATION

Read the package leaflet before use.

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

500 IU C1-esterase inhibitor, human
(50 IU/ml reconstituted solution)

6. OTHER

CSL Behring GmbH, 35041 Marburg, Germany

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS (DILUENT LABEL)

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Water for injections

2. METHOD OF ADMINISTRATION

- not applicable -

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

10 ml

6. OTHER

Do not freeze.

Keep out of the sight and reach of children!

CSL Behring GmbH, 35041 Marburg, Germany

PARTICULARS TO APPEAR ON THE ADMINISTRATION SET

1. NAME OF THE MEDICINAL PRODUCT

Administration Set

2. STATEMENT OF THE ACTIVE SUBSTANCE(S)

- not applicable -

3. LIST OF EXCIPIENTS

- not applicable -

4. PHARMACEUTICAL FORM AND CONTENTS

- not applicable -

5. METHOD AND ROUTE(S) OF ADMINISTRATION

- not applicable -

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

- not applicable –

7. OTHER SPECIAL WARNING(S), IF NECESSARY

- not applicable -

8. EXPIRY DATE

EXP:

9. SPECIAL STORAGE CONDITIONS

- not applicable -

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

- not applicable -

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

- not applicable -

12. MARKETING AUTHORISATION NUMBER(S)

- not applicable -

13. BATCH NUMBER

LOT

14. GENERAL CLASSIFICATION FOR SUPPLY

- not applicable -

15. INSTRUCTIONS ON USE

- not applicable -

16. INFORMATION IN BRAILLE

- not applicable -