

EU LABELS – EU-LAB (LAB/EU/ENGLISH)

BERIATE® 500

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

Supersedes previous versions

Rev.: 09-FEB-2015 / consolidation acc. to rMRP DE/H/0483/001-004/E/001

Rev.: 30-JAN-2014 / Adaptation to FVIII Core-SPC, QRD, etc.

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

1. NAME OF THE MEDICINAL PRODUCT

Beriate 500 IU powder and solvent for solution for injection or infusion

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Active ingredient: Human coagulation factor VIII 500 IU

3. LIST OF EXCIPIENTS

Other ingredients: glycine, calcium chloride, sodium hydroxide (in small amounts) for pH adjustment, sucrose, sodium chloride*

4. PHARMACEUTICAL FORM AND CONTENTS

Powder and solvent for solution for injection/infusion.

Box containing:

1 vial with powder

1 vial with 5 ml water for injections

1 filter transfer device 20/20

Administration set (inner box):

1 disposable 5 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.**

For intravenous injection or infusion

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

Store in a refrigerator. Do not freeze. Keep the container in the outer carton in order to protect from light.

Cumulative storage at up to 25°C for up to 1 month within the shelf-life.*

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

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

Reconstituted product should be used up within 8 hours.

16. INFORMATION IN BRAILLE

Beriate 500 IU

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]>

PARTICULARS TO APPEAR ON THE OUTER PACKAGING (CARTON ADMINISTRATION SET)

1. NAME OF THE MEDICINAL PRODUCT

Administration set

2. STATEMENT OF 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 REACH AND SIGHT 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 -

**Minimum particulars to appear on small immediate packaging units
(substance label)**

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

Beriate 500 IU Powder and solvent for solution for injection or infusion

Human coagulation factor VIII

2. METHOD OF ADMINISTRATION

For i.v. administration after reconstitution

Read package leaflet before use.

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

500 IU

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

5 ml

6. OTHER

Keep out of the sight and reach of children.

Do not freeze.

CSL Behring GmbH, 35041 Marburg, Germany