

**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