EU-LABELS (LAB/EU/ENGLISH)

MONONINE® 1000

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

Supersedes previous versions
Rev.: 16-SEP-2015 / CCSI update
Rev.: 06-NOV-2014 / Adaptation to FIX Core-SPC, QRD, etc. / RSI

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

1. NAME OF THE MEDICINAL PRODUCT

Mononine 1000
1000 IU
powder and solvent for solution for injection/infusion

2. STATEMENT OF ACTIVE SUBSTANCE(S)

1000 IU human coagulation factor IX (100 IU/ml)

3. LIST OF EXCIPIENTS

Other ingredients: histidine, mannitol, sodium chloride*, HCl or NaOH (in small amounts for pH adjustment)

4. PHARMACEUTICAL FORM AND CONTENTS

Box containing:
1 vial with powder
1 vial with 10 ml water for injections
1 filter transfer device 20/20
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.
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

Do not use if package is opened or damaged.

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator. Do not freeze. Keep the vial in the outer carton in order to protect from light.
Do not refrigerate after reconstitution.

This pack may be stored at room temperature (max. +25 °C) for up to 1 month during the shelf life:
Start (date) _____ End (date) _____
Do not put back into the refrigerator after it has been stored at room temperature. If not used, the product must be disposed of.

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

Discard unused solution 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

Made up solution should be used up within 24 hours.

16. INFORMATION IN BRAILLE

- country-specific –

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 SIGHT AND REACH OF CHILDREN

- not applicable -

7. OTHER SPECIAL WARNING(S), IF NECESSARY

- not applicable -

8. EXPIRY DATE

Exp. date

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 No.

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

Mononine 1000

Powder for solution for injection/infusion
For i.v. use

2. METHOD OF ADMINISTRATION

Read package leaflet before use.

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

1000 IU

6. OTHER

CSL Behring GmbH**,** 35041 Marburg, Germany

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

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

Water for injections

2. METHOD OF ADMINISTRATION

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

10 ml

6. OTHER

Keep out of the sight and reach of children.
Do not freeze.

CSL Behring GmbH, 35041 Marburg, Germany