1.3.1 Labelling

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON

1. NAME OF THE MEDICINAL PRODUCT

[Nationally approved name] 2.5 mg/ml powder for concentrate for solution for infusion
Bendamustine hydrochloride

2. STATEMENT OF ACTIVE SUBSTANCE(S)

One vial contains 25 mg of bendamustine hydrochloride (as monohydrate).
One vial contains 100 mg of bendamustine hydrochloride (as monohydrate).

After reconstitution 1 ml of concentrate contains 2.5 mg of bendamustine hydrochloride (as monohydrate).

3. LIST OF EXCIPIENTS

Excipient: Mannitol

4. PHARMACEUTICAL FORM AND CONTENTS

Powder for concentrate for solution for infusion

25 mg/vial
5 x 1 vial
10 x 1 vial
20 x 1 vial

100 mg/vial
1 x 1 vial
5 x 1 vial

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For single use only.

Read the package leaflet before use.

The product must be diluted following reconstitution.

For intravenous 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

CYTOTOXIC

8. EXPIRY DATE

EXP:

9. SPECIAL STORAGE CONDITIONS

This medicinal product does not require any special temperature storage conditions.
Keep the vial in the outer carton in order to protect from light.

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

LOT:

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

<Justification for not including Braille accepted>

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC:
SN:
NN:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

10 ml VIAL

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

[Nationally approved name] 2.5 mg/ml powder for concentrate for solution for infusion

Bendamustine hydrochloride

For IV use after reconstitution and dilution.

2. METHOD OF ADMINISTRATION

3. EXPIRY DATE

EXP:

4. BATCH NUMBER

LOT:

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

25 mg

6. OTHER

CYTOTOXIC

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

50 ml VIAL

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

[Nationally approved name] 2.5 mg/ml powder for concentrate for solution for infusion

Bendamustine hydrochloride

2. STATEMENT OF ACTIVE SUBSTANCE(S)

1 vial contains 100 mg of bendamustine hydrochloride (as monohydrate).

After reconstitution 1 ml of concentrate contains 2.5 mg of bendamustine hydrochloride (as monohydrate).

3. LIST OF EXCIPIENTS

Excipient: Mannitol

4. PHARMACEUTICAL FORM AND CONTENTS

Powder for concentrate for solution for infusion

100 mg

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For single use only.

The product must be diluted following reconstitution.

For intravenous 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

CYTOTOXIC

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

LOT:

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

<Justification for not including Braille accepted>

17. UNIQUE IDENTIFIER – 2D BARCODE

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA