1.3.1 Labelling - Core

PARTICULARS TO APPEAR ON THE OUTER PACKAGING
Outer carton

1 NAME OF THE MEDICINAL PRODUCT

[Product name] <1 3.5 mg> <powder for solution for injection>
<bortezomib> *(to be added to the labelling in case of a branded product name)*

2 STATEMENT OF ACTIVE SUBSTANCE(S)

Each vial contains 1 3.5 mg bortezomib (as a mannitol boronic ester).

3 LIST OF EXCIPIENTS

Mannitol (E421)

4 PHARMACEUTICAL FORM AND CONTENTS

Powder for solution for injection
1 vial

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Subcutaneous or Intravenous use only.
For single use only.
Do not give by other routes.
Intravenous use: Add 1 3.5 ml 0.9% Sodium Chloride to make 1 mg/ml final concentration.
Subcutaneous use: Add 1.4 ml 0.9% Sodium Chloride to make 2.5 mg/ml final concentration.

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. Special handling instructions.

8 EXPIRY DATE

EXP.: {mm/yyyy}

If not used immediately, [product name] reconstituted with 0.9% sodium chloride solution is stable for 8 hours at 25°C/60%RH in the dark, both in a vial and in a polypropylene syringe.

9 SPECIAL 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

Any unused product or waste material should be disposed of in accordance with local requirements.

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

Batch No.:

14 GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription

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
Vial

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

[product name] <1 3.5 mg> <powder for solution for injection>
<bortezomib> *(to be added to the labelling in case of a branded product name)*
Subcutaneous or Intravenous use only.

2 METHOD OF ADMINISTRATION

3 EXPIRY DATE

EXP.: {mm/yyyy}

4 BATCH NUMBER < DONATION AND PRODUCT CODES

Batch No.:

5 CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

1 3.5 mg

6 OTHER