

1.3.1 Labelling - Core

PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING

Outer carton and Label

1 NAME OF THE MEDICINAL PRODUCT

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

bendamustine hydrochloride (*to be added to the labelling in case of a branded product name*)**2 STATEMENT OF ACTIVE SUBSTANCE(S)**

Each vial contains 25 mg bendamustine hydrochloride

Each vial contains 100 mg bendamustine hydrochloride

After reconstitution 1 ml of the concentrate contains 2.5 mg bendamustine hydrochloride

3 LIST OF EXCIPIENTS

Excipient: Mannitol.

4 PHARMACEUTICAL FORM AND CONTENTS

Powder for concentrate for solution for infusion

25 mg

100 mg

[Please refer to the procedure-specific annexes to this core Labelling for the procedure-specific contents (pack sizes).]

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

Reconstitute and dilute before use.

Intravenous use only.

Single use vial

The solution is administered by intravenous infusion over 30-60 min.

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: Handle with caution

8 EXPIRY DATE

EXP.: {mm/yyyy}

9 SPECIAL STORAGE CONDITIONS

Keep the vial in the outer carton in order to protect from light
Shelf life after reconstitution and dilution: 3.5 hours at 25 °C/ 60% RH and 2 days at 2 °C to 8 °C

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

Any unused medicinal 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

[To be completed nationally]

15 INSTRUCTIONS ON USE

16 INFORMATION IN BRAILLE