

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING
Carton

Comment [piq-qrd1]: It refers only to the carton, therefore only the first part should be mentioned.

Deleted: AND THE IMMEDIATE PACKAGING

1. NAME OF THE MEDICINAL PRODUCT

{Invented name} 30 mg solution for injection, pre-filled syringe
Icatibant

Deleted: ,

2. STATEMENT OF ACTIVE SUBSTANCE(S)

30 mg icatibant.

Comment [piq-qrd2]: It has to be inline with section 2 of the SPC. (as acetate)???

3. LIST OF EXCIPIENTS

Contains: acetic acid glacial, sodium hydroxide, sodium chloride, water for injections.

4. PHARMACEUTICAL FORM AND CONTENTS

Comment [piq-qrd3]: Reference to the needle should also be included.

Solution for injection,
1 pre-filled syringe.

Deleted: , pre-filled syringe.

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use,
[Read the package leaflet before use](#)

Deleted: .

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

▼ **Deleted:** Read the package leaflet before use.

8. EXPIRY DATE

EXP

Deleted: : [month/year]

9. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Do not freeze.

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

XXXX
XXXX

12. MARKETING AUTHORISATION NUMBER(S)

EU/0/00/000/000

13. BATCH NUMBER

Lot  Deleted: : {number}

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

{Invented name} 30 mg

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{Blister tray lid}

1. NAME OF THE MEDICINAL PRODUCT

{Invented name} 30 mg solution for injection, pre-filled syringe
Icatibant

Deleted: ,

2. NAME OF THE MARKETING AUTHORISATION HOLDER

XXXXX

3. EXPIRY DATE

EXP

Deleted: : [month/year]

4. BATCH NUMBER

Lot

Deleted: : [number]

5. OTHER

Subcutaneous use

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Syringe label}

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

{Invented name} 30 mg solution for injection, pre-filled syringe

Icatibant

[Subcutaneous use](#)

2. METHOD OF ADMINISTRATION

▼ Deleted: Subcutaneous use¶

3. EXPIRY DATE

EXP ▼ Deleted: [month/year]

4. BATCH NUMBER

Lot ▼ Deleted: : [number]

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

▼ 3 ml Deleted: Icatibant 30 mg/

6. OTHER

XXXX

Formatted: Bullets and Numbering

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I.
II.