Part VI: Summary of the risk management plan

Summary of risk management plan for Icatibant 30 mg solution for injection in pre-filled syringe

This is a summary of the risk management plan (RMP) for Icatibant 30 mg. The RMP details important risks of Icatibant 30 mg solution for injection in pre-filled syringe, how these risks can be minimised, and how more information will be obtained about Icatibant's 30 mg risks and uncertainties (missing information).
Icatibant's 30 mg summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Icatibant 30 mg solution for injection in pre-filled syringe should be used.

I. The medicine and what it is used for

Icatibant 30 mg solution for injection in pre-filled syringe is authorised for symptomatic treatment of acute attacks of hereditary angioedema (HAE) (see SmPC for the full indication). It contains icatibant as the active substance and it is given by subcutaneous injection.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Icatibant 30 mg, together with measures to minimise such risks and the proposed studies for learning more about Icatibant 30 mg's risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

If important information that may affect the safe use of Icatibant 30 mg is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Icatibant 30 mg are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered.
Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Icatibant 30 mg. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this

association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine).

List of important risks and missing information	
Important identified risks	Injection site reactions
Important potential risks	Deterioration of cardiac function under ischaemic conditions due to bradykinin antagonism Partial bradykinin agonism (excluding injection site reactions) Antigenicity manifesting as drug hypersensitivity and lack of efficacy Lack of efficacy Medication errors Effect on reproductive hormone levels in pubertal/ post-pubertal children
Missing information	Use during pregnancy and lactation Use in children below 2 years of age

II.B Summary of important risks

Important Identified Risk: Injection site reaction	
Risk minimisation measures	**Routine risk minimisation measures:** Injection site reactions are described in the SmPC Section 4.8 Undesirable effects. **Additional risk minimisation measures:** None.

Important Potential Risk: Deterioration of cardiac function under ischaemic conditions due to bradykinin antagonism	
Risk minimisation measures	**Routine risk minimisation measures:** Ischaemic heart disease addressed in Section 4.4 of the SmPC. **Additional risk minimisation measures:** None.

Important Potential Risk: Partial bradykinin agonism (excluding injection site reactions)

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Risk minimisation measures	**Routine risk minimisation measures:** None proposed. **Additional risk minimisation measures:** None.

Important Potential Risk: Antigenicity manifesting as drug hypersensitivity and lack of efficacy	
Risk minimisation measures	**Routine risk minimisation measures:** Contraindications in Section 4.2 of the SmPC. Immunogenicity described in Section 4.8 of the SmPC **Additional risk minimisation measures:** None.

Important Potential Risk: Lack of efficacy	
Risk minimisation measures	**Routine risk minimisation measures:** Sections 4.2 and 4.4 of the SmPC **Additional risk minimisation measures:** None.

Important Potential Risk: Medication errors	
Risk minimisation measures	**Routine risk minimisation measures:** Sections 4.1 and 4.2 of the SmPC **Additional risk minimisation measures:** None.

Important Potential Risk: Effect on reproductive hormone levels in pubertal/ post-pubertal children	
Risk minimisation measures	**Routine risk minimisation measures:** Sections 4.6 and 4.8 of the SmPC **Additional risk minimisation measures:** None.

Missing Information: Use during pregnancy and lactation

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Risk minimisation measures	**Routine risk minimisation measures:** Text in the SmPC: • Section 4.6 Fertility, pregnancy, and lactation **Additional risk minimisation measures:** None.

Missing Information: Use in children below 2 years of age	
Risk minimisation measures	**Routine risk minimisation measures:** Text in the SmPC: Indication in Section 4.1. Section 4.2 (Posology and method of administration) **Additional risk minimisation measures:** None.

II.C Post authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Icatibant 30 mg.

II.C.2 Other studies in post-authorisation development plan

There are no studies required for Icatibant 30 mg.