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

This is a summary of the risk management plan (RMP) for Icatibant Accord 30 mg solution for injection in pre-filled syringe. The RMP details important risks of Icatibant Accord 30 mg solution for injection in pre-filled syringe, how these risks can be minimised, and how more information will be obtained about Icatibant Accord 30 mg solution for injection in pre-filled syringe risks and uncertainties (missing information).

Icatibant Accord 30 mg solution for injection in pre-filled syringe's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Icatibant Accord 30 mg solution for injection in pre-filled syringe should be used.

This summary of the RMP for Icatibant Accord 30 mg solution for injection in pre-filled syringe should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of Icatibant Accord 30 mg solution for injection in pre-filled syringe's RMP.

I. The medicine and what it is used for

Icatibant Accord is indicated for symptomatic treatment of acute attacks of hereditary angioedema (HAE) in adults, adolescents and children aged 2 years and older, with C1-esterase-inhibitor deficiency.

It contains Icatibant as the active substance and it is administered by subcutaneous route.

Further information about the evaluation of Icatibant Accord 30 mg solution for injection in pre-filled syringe's benefits can be found in Icatibant Accord 30 mg solution for injection in pre-filled syringe's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage https://www.ema.europa.eu/en/medicines/human/EPAR/icatibant-accord.

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

Important risks of Icatibant Accord 30 mg solution for injection in pre-filled syringe, together with measures to minimise such risks and the proposed studies for learning more about Icatibant Accord 30 mg solution for injection in pre-filled syringe'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 including signal management activity, 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 Accord 30 mg solution for injection in pre-filled syringe is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Icatibant Accord 30 mg solution for injection in pre-filled syringe are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. 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 Accord 30 mg solution for injection in pre-filled syringe. 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).

Important identified risk	• Injection site reactions
Important potential risk	• 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 in pregnant and lactating women • Use in children below 2 years of age

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

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 authorization or specific obligation of Icatibant Accord 30 mg solution for injection in pre-filled syringe.

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

There are no studies required for Icatibant Accord 30 mg solution for injection in pre-filled syringe as post-authorisation development plan.