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 solution for injection in pre-filled syringe (hereinafter referred to as Icatibant). The RMP details important risks of Icatibant, how these risks can be minimised, and how more information will be obtained about product's / Icatibant's risks and uncertainties (missing information).

Icatibant's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Icatibant should be used.

Important new concerns or changes to the current ones will be included in updates of Icatibant's RMP.

I. The Medicine and What It is used for

Icatibant is authorised 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 (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, together with measures to minimise such risks and the proposed studies for learning more about Icatibant'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 is not yet available, it is listed under 'missing information' below.

II.A List of Important Risks and Missing Information

Important risks of Icatibant 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. 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).

Table 4: Summary of Safety Concerns

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 in pregnant and lactating women • Use in children less than 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 authorisation or specific obligation of Icatibant.