Summary of risk management plan for Inpremzia 1 international unit/mL solution for infusion (insulin human)

This is a summary of the risk management plan (RMP) for Inpremzia 1 international unit/mL solution for infusion (hereafter referenced as Inpremzia). The RMP provides details on the risks of Inpremzia, and how these risks can be minimized.

The summary of product characteristics (SmPC) and package leaflet (PL) for Inpremzia provide essential information to healthcare professionals (HCP) and patients on how the product should be used.

This summary of the RMP for Inpremzia should be read in the context of all other related information, including the assessment report of the evaluation and its plain-language summary, all of which are part of the European Public Assessment Report (EPAR).

New safety concerns and/or changes to the current safety concerns will be included in future updates of the RMP.

I. The medicine and what it is used for

Inpremzia is authorized for the treatment of diabetes mellitus. It contains insulin human as the active substance, and it is given by intravenous infusion.

Further information about the evaluation of Inpremzia's benefits can be found in the EPAR, including in its plain-language summary, available on the European Medicines Agency (EMA) website under the medicine's webpage:

https://www.ema.europa.eu/en/medicines/human/EPAR/inpremzia

II. Risks associated with the medicine and activities to minimize or further characterize the risks

There are no risks included in the RMP for Inpremzia; however, measures to minimize the risks for any medicinal products may be:

- Specific information, such as warnings, precautions, and advice on correct use, in the PL and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorized pack size – the amount of medicine in a pack is chosen so as to ensure that the medicine is used correctly;

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- The medicine's legal status – the way a medicine is supplied to the patient (e.g., with or without prescription) can help to minimize its risks.

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

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, including periodic safety update report assessment, so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

II.A List of important risks and missing information

Important risks of medicinal products are risks that need special risk management activities to further investigate or minimize 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 medicinal products. Potential risks are concerns for which an association with the use of the medicinal product is possible based on available data, but this association has not been established yet and needs to be further monitored. Missing information refers to information on the safety of the medicinal product that is currently missing and further information may need to be collected (e.g., on the long-term use of the medicine).

There are no safety concerns for Inpremzia.

II.B Summary of important risks and missing information

There are no safety concerns included in this RMP. All risks associated with the use of Inpremzia are considered adequately characterized and appropriately managed with routine risk minimization measures in the product information which are fully integrated into standard clinical practice.

II.C Post-authorization development plan

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

There are no studies which are conditions of the marketing authorization or specific obligations of Inpremzia.

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

There are no studies required for Inpremzia.

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