Summary of the risk management plan for Actraphane (human insulin rDNA)

This is a summary of the risk management plan (RMP) for Actraphane. The RMP details important risks of Actraphane, how these risks can be minimised, and how more information will be obtained about Actraphane's risks and uncertainties (missing information).

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

This summary of the RMP for Actraphane should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all of 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 Actraphane's RMP.

I. The medicine and what it is used for

Actraphane is authorised for the treatment of diabetes mellitus. It contains human insulin (HI) as the active substance and it is given by subcutaneous route.

Further information about the evaluation of Actraphane's benefits can be found in Actraphane's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage.

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

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

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

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- 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 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 public (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 AEs is collected continuously and regularly analysed 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 Actraphane 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 Actraphane. 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	None
Important potential risks	Medication errors (including human error-related medication errors)
Missing information	None

II.B Summary of important risks

Medication errors (including human error-related medication errors)	
Evidence for linking the risk to the medicine	Market experience: Post-marketing data include events from all valid cases reported from different sources excluding clinical trials, that is, spontaneous (including literature) sources, non-interventional studies and other solicited sources.
Risk factors and risk groups	Patients treated with more than one type of insulin New insulin users Elderly patients Users with visual impairment Change in insulin regimen or type of administration (e.g., CSII to pen device) Patients not self-administering their insulin Similar naming of different insulin products

	Similar appearances of devices
Risk minimisation measures	*Routine risk minimisation measures:* • SmPC Section 4.2 where information is given on posology and method of administration. • SmPC Section 6.4 where special precautions for storage are given. • SmPC Section 6.6 where special precautions are given for disposal and other handling. • PL Section 2 with information on when the medicine should not be used, and also to check the label before use to ensure the right type of medicine is used. • PL Section 3 with information on how to use the product. • PL Section 5 with information on how to store the product. • IFU where information is given on how to handle the product including instruction to check the label to ensure the right type of insulin is used and instruction on how to avoid injection of air to ensure proper dosing. • Product differentiation strategy; includes trade names, label text, colour branding of the carton and container label.

Abbreviations: CSII = continuous subcutaneous insulin infusion; IFU = instructions for use; PL = package leaflet; SmPC = Summary of Product Characteristics.

II.C Post-authorisation development plan

Not applicable.