Summary of the risk management plan for Actrapid (human insulin)

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

Actrapid's Summary of Product Characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals and patients on how Actrapid should be used.

This summary of the RMP for Actrapid 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 reports (EPAR).

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

I. The medicine and what it is used for

Actrapid is authorised for the treatment of diabetes mellitus. It contains human insulin as the active substance and it is given by subcutaneous or intravenous route.

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

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

Important risks of Actrapid, together with measures to minimise such risks and the proposed studies for learning more about Actrapid'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 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 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 events (AEs) is collected continuously and regularly analysed, including PSUR 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 Actrapid 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 Actrapid. 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	None
Missing information	None

II.B Summary of important risks

No risks of Actrapid need special risk management or pharmacovigilance activities for further characterisation.

II.C Post-authorisation development plan

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

There are no studies that are conditions of the marketing authorisation or specific obligation of Actrapid.

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

No studies are required for Actrapid.