SUMMARY OF RISK MANAGEMENT PLAN FOR TRUVELOG MIX 30 (INSULIN ASPART)

This is a summary of the risk management plan (RMP) for TRUVELOG MIX 30. The RMP details important risks of TRUVELOG MIX 30, how these risks can be minimized, and how more information will be obtained about TRUVELOG MIX 30's risks and uncertainties (missing information).

TRUVELOG MIX 30 summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals (HCPs) and patients on how TRUVELOG MIX 30 should be used.

This summary of the RMP for TRUVELOG MIX 30 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 TRUVELOG MIX 30's RMP.

I. THE MEDICINE AND WHAT IT IS USED FOR

TRUVELOG MIX 30 is proposed for treatment of diabetes mellitus in adults, adolescents and children aged 10 years and above. It contains soluble insulin aspart/protamine-crystallized insulin aspart as the active substance and it is injected by subcutaneous (SC) route.

Further information about the evaluation of TRUVELOG MIX 30 benefits will be found in TRUVELOG MIX 30's EPAR, including the 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/truvelog-mix-30

II. RISKS ASSOCIATED WITH THE MEDICINE AND ACTIVITIES TO MINIMIZE OR FURTHER CHARACTERIZE THE RISKS

Important risks of TRUVELOG MIX 30, together with measures to minimize such risks and the proposed studies for learning more about TRUVELOG MIX 30 risks, are outlined in the next sections.

Measures to minimize 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 HCPs;
- Important advice on the medicine's packaging;

- The authorized pack size - the amount of medicine in a pack is chosen to ensure that the medicine is used correctly;
- The medicine's legal status - the way a medicine is supplied to the patient (eg, 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 (PSUR) assessments 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 TRUVELOG MIX 30 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 either identified or potential risks. Identified risks are concerns for which there is sufficient proof of a link with the use of TRUVELOG MIX 30. 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 (eg, on the long-term use of the medicine);

Table 1 - List of important risks and missing information

Important identified risk	None
Important potential risk	None
Missing information	None

II.B Summary of important risks

Not applicable

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 obligation of TRUVELOG MIX 30.

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

There are no studies required for TRUVELOG MIX 30.

SUMMARY OF RISK MANAGEMENT PLAN FOR INSULIN ASPART SANOFI (INSULIN ASPART)

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

INSULIN ASPART SANOFI summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals (HCPs) and patients on how INSULIN ASPART SANOFI should be used.

This summary of the RMP for INSULIN ASPART SANOFI 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 INSULIN ASPART SANOFI's RMP.

I. THE MEDICINE AND WHAT IT IS USED FOR

INSULIN ASPART SANOFI is authorized for treatment of diabetes mellitus in adults, adolescents and children aged 1 year and above (see SmPC for the full indication). It contains insulin aspart as the active substance and it is injected by subcutaneous (SC) route. INSULIN ASPART SANOFI can also be used for continuous SC insulin infusion and can be given intravenously (IV) by HCPs.

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

https://www.ema.europa.eu/en/documents/assessmentreport/insulin-aspart-sanofiepar-public-assessmentreport_en.pdf

II. RISKS ASSOCIATED WITH THE MEDICINE AND ACTIVITIES TO MINIMIZE OR FURTHER CHARACTERIZE THE RISKS

Important risks of INSULIN ASPART SANOFI, together with measures to minimize such risks and the proposed studies for learning more about INSULIN ASPART SANOFI risks, are outlined in the next sections.

Measures to minimize 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 HCPs;

- Important advice on the medicine's packaging;
- The authorized pack size - the amount of medicine in a pack is chosen to ensure that the medicine is used correctly;
- The medicine's legal status - the way a medicine is supplied to the patient (eg, 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 (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 INSULIN ASPART SANOFI 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 either identified or potential risks. Identified risks are concerns for which there is sufficient proof of a link with the use of INSULIN ASPART SANOFI. 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 (eg, on the long-term use of the medicine);

Table 1 - List of important risks and missing information

Important identified risk	None
Important potential risk	None
Missing information	None

II.B Summary of important risks

Not applicable

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 obligation of INSULIN ASPART SANOFI.

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

There are no studies required for INSULIN ASPART SANOFI.