

Summary of risk management plan for Insulin aspart Sanofi (Insulin aspart)

This is a summary of the 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's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals 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 route.

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

<https://www.ema.europa.eu/en/medicines/human/EPAR/insulin-aspart-sanofi>

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

There are no important risks or missing information considered as relevant for Insulin aspart Sanofi's RMP.

II.A. List of important risks and missing information

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 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.