RMP Summary

Fiasp® *ultra-fast-acting*

(insulin aspart)

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Disclaimer

The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks as well as to prevent or minimise them.

The RMP summary of Fiasp® *ultra-fast-acting* is a concise document and does not claim to be exhaustive.

As the RMP is an international document, the summary might differ from the "Arzneimittelinformation / Information sur le médicament" approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorization.

Please note that the reference document which is valid and relevant for the effective and safe use of Fiasp® *ultra-fast-acting* in Switzerland is the "Arzneimittelinformation / Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic.

Novo Nordisk Pharma AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of Fiasp® *ultra-fast-acting*.

Summary of the risk management plan for Fiasp (insulin aspart)

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

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

This summary of the RMP for Fiasp 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 Fiasp's RMP.

I. The medicine and what it is used for

Fiasp is authorised for treatment of diabetes mellitus in adults, adolescents and children above 1 year of age (see SmPC for the full indication). It contains insulin aspart as the active substance and it is given intravenously or subcutaneously.

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

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

Important risks of Fiasp, together with measures to minimise such 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 package leaflet 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 minimises its risks.

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

In addition to these measures, information about adverse events is collected continuously and regularly analysed, 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 Fiasp 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 Fiasp. 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

This section is not applicable as there are no important risks for Fiasp.

II.C Post-authorisation development plan

This section is not applicable as there are no imposed post-authorisation efficacy studies ongoing or planned for Fiasp.