Summary of risk management plan for insulin aspart (Fiasp, NovoRapid and NovoMix)

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

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

This summary of the RMP for insulin aspart 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's RMP.

I. The medicine and what it is used for

Fiasp

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.

NovoRapid

NovoRapid is authorised 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. NovoRapid is administered by subcutaneous injection. NovoRapid can also be used for CSII and can be given intravenously by HCPs.

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

NovoMix

NovoMix is authorised for treatment of diabetes mellitus (see SmPC for the full indication). It contains insulin aspart as the active substance, and it is given by subcutaneous injection.

Further information about the evaluation of benefits of NovoMix can be found in EPAR for NovoMix, 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

Fiasp

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 PSUR assessment, so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

NovoRapid

Important risks of NovoRapid, together with measures to minimise such risks and the proposed studies for learning more about risks of NovoRapid, 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 HCPs
- 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 PSUR assessment, so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

NovoMix

Important risks of NovoMix, together with measures to minimise such risks and the proposed studies for learning more about risks of NovoMix, 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 HCPs
- 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 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

Fiasp

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

NovoRapid

Important risks of NovoRapid 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 NovoRapid. 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). An overview of important risks and missing information for NovoRapid is provided in the table below.

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	None

NovoMix

Important risks of NovoMix 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 NovoMix. 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). An overview of important risks and missing information for NovoMix is provided in the table below.

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

Fiasp

There are no important risks for Fiasp.

NovoRapid

There are no important risks for NovoRapid.

NovoMix

There are no important risks for NovoMix.

II.C Post-authorisation development plan

Fiasp

There are no imposed post-authorisation efficacy studies ongoing or planned for Fiasp.

NovoRapid

There are no imposed post-authorisation efficacy studies ongoing or planned for NovoRapid.

NovoMix

There are no imposed post-authorisation efficacy studies ongoing or planned for NovoMix.

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

Fiasp

As part of the agreement for marketing authorisation in China, Novo Nordisk is studying efficacy and safety of Fiasp Aspart compared to NovoRapid both in combination with insulin degludec with or without metformin in Chinese adults with type 1 or type 2 diabetes (trial NN1218-4357). Further, a phase 1 trial investigating the pharmacokinetic properties of Fiasp in Chinese Subjects with Type 1 Diabetes (trial NN1218-4316) is conducted during 2021 and 2022.

NovoRapid

There are no studies imposed as conditions of marketing authorisation for NovoRapid.

NovoMix

There are no studies which are conditions of the marketing authorisation for NovoMix.

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

Fiasp

There are no other studies in the post-authorisation development plan for Fiasp.

NovoRapid

There are no other studies in the post-authorisation development plan for NovoRapid.

NovoMix

There are no other studies in the post-authorisation development plan for NovoMix.