Fiasp® *ultra-fast-acting* (Insulin Aspart) - Injection solution

Summary of the risk management plan (RMP) for Fiasp® *ultra-fast-acting*

Based on RMP v4.0

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Table of Contents

Page

1 Summary of the risk management plan (RMP) for Fiasp® *ultra-fast-acting*

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 minimize 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.swissmedicinfo.ch) approved and authorized by Swissmedic. Novo Nordisk Pharma AG is fully responsible for the accuracy and correctness of the content of the here published summary RMP of Fiasp® *ultra-fast-acting*.

2 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 Fiasp®'s benefits can be found in Fiasp®'s EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage: EPAR link.

3 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 the case of Fiasp®, these measures are supplemented with *additional risk minimisation* measures mentioned under relevant risks, below.

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*.

3.1 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	Medication errors (mainly wrong drug administered)
Important potential risks	None
Missing information	None

3.2 Summary of important risks

Medication errors (mainly wrong drug administered)	
Evidence for linking the risk to the medicine	Medication error is a well-known risk in diabetic patients treated with multiple insulins. Medication errors can lead to clinical consequences such as hypoglycaemia or hyperglycaemia. In clinical trials with Fiasp®, medication errors (mainly wrong drug administered) occurred with pen injectors which were

	packaged and labelled specifically for use in these trials. The final packaging and labelling for the marketed products has been developed and optimised in order to minimise the potential for wrong drug administration due to product mix-up. Even with these differentiation features, there is a risk for medication error, which is therefore considered an important identified risk for Fiasp®. Administration of a wrong type of insulin can occur due to mix-up by the patient, prescription errors or dispensing errors at the pharmacy.
Risk factors and risk groups	• Patients treated with more than one type of insulin • New insulin users • Elderly patients • Users with visual impairment • Change in insulin regimen or type of administration • Similar naming of different insulin products • Similar appearances of devices
Risk minimisation measures	***Routine risk communication:*** None ***Routine risk minimisation activities recommending specific clinical measures to address the risk:*** <u>Product differentiation strategy:</u> • Coloured cartons, labels and plastic components of primary packaging to prevent wrong drug administration due to mix-up of different insulin products • A Penfill cartridge is not compatible with the currently available pumps intended for use with PumpCart and vice versa. <u>Text in SmPC, PL and IFU</u> • SmPC Section 4.2 where information is given on posology and method of administration. • SmPC Section 4.2 where passive discouragement for withdrawing insulin with a syringe from cartridges and pre-filled pens is included. It is further specified that if

	administration by syringe, intravenous injection or infusion pump is necessary, a vial should be used. • Section 4.4 Special warnings and precautions for use where information on avoidance of accidental mix-ups is given. Additionally, advice on practical actions to minimise the risk is given, for example for patients to check the insulin label before each injection and that a syringe should never be used to draw the medicinal product from the cartridge of a pre-filled pen. • SmPC Section 6.6 where special precautions are given for disposal and other handling. Text/wording allowing the possibility to withdraw insulin from cartridges and pre-filled pens with a syringe in case of emergency has been deleted from this section. • PL Section 2 with information on when the medicine should not be used, and also to check the label before use to ensure the right type of medicine is used. • PL Section 3 with information on o How to use the product correctly o Carrying a spare cartridge (Penfill and PumpCart) o Having a pen-injector or similar available in case of pump failure, for pump users o Correct usage of Fiasp® in patients with poor eyesight • IFU where information is given on how to handle the product including instruction to check the label to ensure the right type of insulin is used and instruction on how to avoid injection of air to ensure proper dosing and to carry a spare pre-filled pen in case it is lost or damaged. ***Additional risk minimisation measures:*** To increase awareness of the differences between Fiasp® and Tresiba® products, a communication plan regarding the risk of mix-up between Fiasp® and Tresiba® has been prepared. The communication plan includes a direct healthcare professional communication (DHPC) addressing pharmacies and dispensing clinics. This risk minimisation is intended to be used until there

	are no longer any Fiasp® products on the market with only yellow colour plastic components.
Additional pharmacovigilance activities	*None*

Abbreviations: DHPC = direct healthcare professional communication; IFU = information for use; PL = product leaflet.

3.3 Post-authorisation development plan

3.3.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Fiasp®.

3.3.2 Other studies in post-authorisation development plan

No studies are required for Fiasp®.