Summary of the Risk Management Plan (RMP) for SULIQUA®

SULIQUA® (lixisenatide + insulin glargine)
Marketing Autorisation Holder : sanofi-aventis (suisse) sa
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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 minimize them. This RMP summary 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 medicament” 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 the product in Switzerland is the “Arzneimittelinformation/ Information sur le medicament” (see www.swissmedicinfo.ch) approved and authorized by Swissmedic. Sanofi-aventis(suisse)sa is fully responsible for the accuracy and correctness of the content of this published RMP summary.

1. THE MEDICINE AND WHAT IT IS USED FOR

According to Swiss label

Suliqua is used in combination with metformin for the treatment of type 2 diabetes in adults when metformin alone, combination therapy with metformin and sulfonylurea, metformin in combination with a GLP-1 receptor agonist, or combination therapy with metformin and basal insulin does not provide adequate glycemic control.

According to EU SmPC

SULIQUA is authorized for the treatment of adults with insufficiently controlled Type 2 diabetes mellitus (T2DM) to improve glycaemic control as an adjunct to diet and exercise in addition to metformin with or without sodium-glucose co-transporter-2 inhibitors (SGLT-2) (see SmPC for the full indication). It contains lixisenatide and insulin glargine as the active substances and it is given by subcutaneous (SC) route.

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

Refer to EPAR available on the EMA website at the following link:
https://www.ema.europa.eu/documents/product-information/suliqua-epar-product-information_en.pdf

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

Important risks of SULIQUA, together with measures to minimize such risks and the proposed studies for learning more about SULIQUA's 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, Instructions for use (IFU) 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 so 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 the case of SULIQUA, these measures are supplemented with additional risk minimization measures mentioned under relevant important risks, outlined in the next sections.

In addition to these measures, information about adverse reactions 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.

2.1. List of important risks and missing information

Important risks of SULIQUA 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 identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of SULIQUA. 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	Medication errors including mix-ups between the different strength of the product
Missing information	None

2.2. Summary of important risks

Table 2 – Important potential risk: Medication errors including mix-ups between the different strength of the product with corresponding risk minimization activities

Medication errors including mix-ups between the different strength of the product	
Evidence for linking the risk to the medicine	Clinical trials Human factor study Literature Postmarketing data
Risk factors and risk groups	New patients switching to SULIQUA and vice versa. Visually impaired patients using SULIQUA unassisted.
Risk minimization measures	Routine risk minimization measures: • **Mix-up between long acting (basal) and short acting (bolus) insulin, including by visually impaired or color blind patients** PL section 2. SmPC sections 4.4 and 6.6. Packaging: - The packaging displays high differentiation in color and presentation fromother compound - Safety message “for single patient use only” prevents sharing treatment with

Medication errors including mix-ups between the different strength of the product	
	other patients. Prescription only medicine. • **Mix-up between different SULIQUA strengths, including by visuallyimpaired or color blind patients** SmPC sections 4.2 and 4.4. PL section 3. Prescription only medicine. • **Non-compliance with instructions for use** SmPC section 4.2. PL section 3. • **Misuse related to extraction of insulin from the pre-filled pen using a syringe** SmPC sections 4.2 and 4.4. IFU: "**Never use a syringe to remove medicine product from your pen**. If you do, you may not get the correct amount of medicine." • **Non-compliance with instructions to use a new needle for each injection** SmPC sections 4.2 and 6.6. PL section 3. IFU: "**Never re-use needles**. If you do you might not get your full dose (underdosing) or get too much (overdosing) as the needle could block." Packaging: The outer carton and label of the prefilled pen include the statement that the product should only be used in the prefilled pen. The outer carton and label include the statement "Always use a new needle". The carton displays a prominent warning about misuse related to extraction of "SULIQUA" from the prefilled pen using a syringe. • **Switching error: from conventional insulin to SULIQUA and vice versa** SmPC sections 2 and 4.2. PL section 3. The use of an adequate pen differentiation after the trade name is needed to identify the two different pens of SULIQUA and minimize the risk of medication errors between the two pen strengths. The final packaging contains the amount of each active ingredient on the package. It also provides the range of insulin glargine that each pen provides. The dose range of each pen 10-40 or 30-60 is noted after the trade name in the SmPC, the PL and the IFU and presented as highlight on the outer packaging and the pen label. The expression of the name of the medicine is displayed as: "SULIQUA SoloStar Insulin glARGine 100 units/ml + 50 micrograms/ml lixisenatide solution for injection in a pre-filled pen, 10-40 dose steps (1 dose step = 1 unit of insulin glARGine + 0.5 micrograms of lixisenatide)" The outer carton includes description of the content of a dose step in the main field of view such that it can be clearly seen. Definition of the dose step only for the type of pen contained (100/33 or 100/50) and not for both pen types.

Medication errors including mix-ups between the different strength of the product	
	The word “SULIQUA” more prominent than “SoloStar”. For the outer carton and pen labels, color of pen and packaging are aligned. Prescription only medicine <u>Additional risk minimization measures:</u> HCP guide and Patient guide (updated)

HCP: Healthcare Professional; IFU: Instructions for Use; PL: Package Leaflet; SmPC: Summary of Product Characteristics.

2.3. Post-authorisation development plan

2.3.1. Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorization or specific obligation of SULIQUA.

2.3.2. Other studies in post-authorisation development plan

There are no studies required for SULIQUA.