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

LYXUMIA® (lixisenatide)
Marketing Autorisation Holder : sanofi-aventis (suisse) sa
RMP version 7.0
Date: 14 March 2022

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

Lyxumia is indicated for the treatment of adults with type 2 diabetes mellitus to ensure glycemic control when oral antidiabetic drugs and/or basal insulin do not provide adequate control.

In combination with the following oral antidiabetic agents:

- metformin
- a sulfonylurea
- a combination of metformin and a sulfonylurea

In combination with basal insulin:

- alone,
- in combination with metformin
- in combination with a sulfonylurea

According to EU SmPC

LYXUMIA is authorized for the treatment of adults with type 2 diabetes mellitus to achieve glycemic control in combination with oral glucose-lowering medicinal products and/or basal insulin when these, together, with diet and exercise, do not provide adequate glycemic control (see SmPC for the full indication). It contains lixisenatide as the active substance and it is given by subcutaneous route (see SmPC for details).

Further information about the evaluation of LYXUMIA's benefits can be found in LYXUMIA'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/lyxumia

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

Important risks of LYXUMIA, together with measures to minimize such risks and the proposed studies for learning more about LYXUMIA'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 and SmPC addressed to patients and healthcare professionals;
- 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 addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, including periodic safety update report 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 LYXUMIA 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 LYXUMIA. 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	None
Missing information	None

2.2. Summary of important risks

Not applicable

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 LYXUMIA.

2.3.2. Other studies in post-authorisation development plan

There are no studies required for LYXUMIA.