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

Praluent® (alirocumab)
Marketing Autorisation Holder : sanofi-aventis (suisse) sa
RMP version 8.0
Date of final sign-off: 20-Dec-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 minimise them. The RMP summary of Praluent® 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 Praluent® 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 summary RMP of Praluent®.

1. THE MEDICINE AND WHAT IT IS USED FOR

According to Swiss label

Praluent is indicated as an adjunct to diet and in addition to a maximum tolerated statin dose, with or without further lipid-lowering therapies, in adults with hypercholesterolemia (including heterozygous familial hypercholesterolemia) who require additional low-density lipoprotein cholesterol (LDL-C) lowering.

Praluent is indicated to reduce the risk of cardiovascular events (myocardial infarction, ischemic stroke, unstable angina requiring hospitalization) in patients with high cardiovascular risk.

For the effect of Praluent on cardiovascular mortality, see section “Properties/Effects”.

According to EU SmPC

PRALUENT is authorized for indications as noted below (see SmPC for the full indication). It contains alirocumab as the active substance and it is given by subcutaneously (SC).

Primary hypercholesterolemia and mixed dyslipidemia

PRALUENT is indicated in adults with primary hypercholesterolemia (heterozygous familial and non-familial) or mixed dyslipidemia, as an adjunct to diet:

- in combination with a statin or statin with other lipid-lowering therapies in patients unable
  to reach low density lipoprotein cholesterol (LDL-C) goals with the maximum tolerated dose of a statin, or
- alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated.

Established atherosclerotic cardiovascular disease

PRALUENT is indicated in adults with established atherosclerotic cardiovascular disease (ASCVD) to reduce cardiovascular risk by lowering LDL-C levels, as an adjunct to correction of other risk factors:

- in combination with the maximum tolerated dose of a statin with or without other lipid-lowering therapies or,
- alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated.

Following the completion of pediatric investigation plan, the marketing authorization holder has proposed the below indication:

Primary hypercholesterolemia and mixed dyslipidemia:

PRALUENT is indicated in adults with primary hypercholesterolemia (heterozygous familial and non-familial) or mixed dyslipidemia, and in pediatric patients 8 years of age and older with heterozygous familial hypercholesterolemia (HeFH) as an adjunct to diet:

- in combination with a statin or statin with other lipid-lowering therapies in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin, or
- alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated.

Established atherosclerotic cardiovascular disease:

PRALUENT is indicated in adults with established atherosclerotic cardiovascular disease to reduce cardiovascular risk by lowering LDL-C levels, as an adjunct to correction of other risk factors:

- in combination with the maximum tolerated dose of a statin with or without other lipid-lowering therapies or,
- alone or in combination with other lipid-lowering therapies in patients who are statin intolerant, or for whom a statin is contraindicated.

Further information about the evaluation of PRALUENT's benefits can be found in PRALUENT'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/praluent

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

Important risks of PRALUENT, together with measures to minimize such risks and the proposed studies for learning more about PRALUENT'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;
- Both healthcare professionals and patients are also provided with packaging information relative to the use of medical device, such as IFU and quick reference guide inside the lid packaging; both elements convey key messages for an optimal use of the medical device;
- 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. Alirocumab is a prescription only medicine.

Together, these measures constitute routine risk minimization measures.

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.

As part of routine surveillance, a “specific pregnancy/drug exposure via parent data collection form” is used to document spontaneous or solicited cases of pregnancy exposed to alirocumab.

In addition, a neonates/children form, added to the pregnancy form has been put in place to document any developmental defects up to 12 months post-birth of children whose mothers are exposed to alirocumab during pregnancy.

If important information that may affect the safe use of PRALUENT is not yet available, it is listed under “missing information” outlined in the next section.

2.1. **List of important risks and missing information**

Important risks of PRALUENT 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 PRALUENT. 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	Systemic hypersensitivity reactions
Important potential risk	None
Missing information	Use in pregnant and lactating women Use in patients with severe hepatic impairment

2.2. Summary of important risks

Table 2 Important identified risk with corresponding risk minimization activities: Systemic hypersensitivity reactions

Systemic hypersensitivity reactions	
Evidence for linking the risk to the medicine	Literature, non-clinical, clinical trials
Risk factors and risk groups	No risk groups or risk factors have been identified. Risk factor analyses included: demographics (age, gender, race, ethnicity, BMI) medical history at baseline, estimated glomerular filtration rate, type of hypercholesterolemia and medical history of allergy, region, statin treatment at randomization.
Risk minimization measures	**Routine risk minimization measures:** • Labelled in sections 4.4 and 4.8 of the SmPC • Labelled in sections 2 and 4 of PL • Prescription only medicine

BMI: Body Mass Index; PL: Package Leaflet; SmPC: Summary of Product Characteristics.

Table 3 – Missing information with corresponding risk minimization activities: Use in pregnant and lactating women

Use in pregnant and lactating women	
Risk minimization measures	**Routine risk minimization measures:** • Labelled in section 4.6 of SmPC • Labelled in section 2 of PL • Prescription only medicine.

PL: Package Leaflet; SmPC: Summary of Product Characteristics.

Table 4 – Missing information with corresponding risk minimization activities: Use in patients with severe hepatic impairment

Use in patients with severe hepatic impairment	
Risk minimization measures	**Routine risk minimization measures:** • Labelled in sections 4.2 and 4.4 of SmPC • Labelled in section 2 of PL • Prescription only medicine.

PL: Package Leaflet; SmPC: Summary of Product Characteristics.

2.3. Post-authorization development plan

2.3.1. *Studies which are conditions of the marketing authorization*

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

2.3.2. *Other studies in post-authorization development plan*

There are no studies required for PRALUENT.

REFERENCES

None