Part VI: Summary of the risk management plan

Summary of risk management plan for Linagliptin Orion

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

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

Important new concerns or changes to the current ones will be included in updates of Linagliptin Orion's RMP.

I. The medicine and what it is used for

Linagliptin Orion is authorised for adults with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control as monotherapy when metformin is inappropriate due to intolerance, or contraindicated due to renal impairment, and as combination therapy in combination with other medicinal products for the treatment of diabetes, including insulin, when these do not provide adequate glycaemic control. It contains linagliptin as the active substance and it is given by mouth.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Linagliptin Orion together with measures to minimise such risks and the proposed studies for learning more about Linagliptin Orion’s 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 patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*. If important information that may affect the safe use of Linagliptin Orion is not yet available, it is listed under ‘missing information’ below.

II.A List of important risks and missing information

Important risks of Linagliptin Orion are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. 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 Linagliptin Orion. 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	Pancreatitis
Important potential risks	Pancreatic cancer
Missing information	Pregnancy/breast-feeding

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

II.C Post-authorisation development plan

There are no studies required for Linagliptin Orion.