Part VI: Summary of the risk management plan

Summary of risk management plan for Linagliptin, HEXAL 5 mg filmtabletta, Linagliptin Sandoz 5 mg filmtabletta, Tingapla 5 mg filmtabletta, Linagliptin 1 A Pharma 5 mg filmtabletta

This is a summary of the risk management plan (RMP) for Linagliptin, HEXAL 5 mg filmtabletta, Linagliptin Sandoz 5 mg filmtabletta, Tingapla 5 mg filmtabletta, Linagliptin 1 A Pharma 5 mg filmtabletta (Sandoz's products containing linagliptin). The RMP details important risks of Sandoz's products containing linagliptin, how these risks can be minimized, and how more information will be obtained about Sandoz's products containing linagliptin's risks and uncertainties (missing information).

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

Important new concerns or changes to the current ones will be included in updates of Sandoz's products containing linagliptin's RMP.

I. The medicine and what it is used for

Linagliptin film-coated tablet are authorized for:

Linagliptin is indicated in adults with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycemic control as:

Monotherapy

- When metformin is inappropriate due to intolerance or contraindicated due to renal impairment.

Combination therapy

- In combination with other medicinal products for the treatment of diabetes, including insulin, when these do not provide adequate glycemic control.

It contains linagliptin as an active substance and is given orally as film-coated tablet (5 mg).

II. Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of Sandoz's products containing linagliptin, together with measures to minimize such risks and the proposed studies for learning more about Sandoz's products containing linagliptin's risks, are outlined below.

Measures to minimize 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 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 (e.g., 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, 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, film-coated tablet is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Sandoz's products containing linagliptin are risks that need special risk management activities to further investigate or minimize 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 Sandoz's products containing linagliptin. 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);

Table 3 Part VI: List of important risks and missing information

List of important risks and missing information	
Important identified risk	Pancreatitis
Important potential risk	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-authorization development plan

II.C.1 Studies which are conditions of the marketing authorization

There are no studies which are conditions of the marketing authorization or specific obligation of Sandoz's products containing linagliptin.

II.C.2 Other studies in post-authorization development plan

There are no studies required for Sandoz's products containing linagliptin.