Part VI: Summary of the Risk Management Plan

Summary of Risk Management Plan for Sitagliptin 25mg, 50mg, 100mg film-coated tablets

This is a summary of the risk management plan (RMP) for Sitagliptin 25mg, 50mg, 100mg film-coated tablets (hereinafter referred to as Sitagliptin). The RMP details important risks of Sitagliptin, how these risks can be minimised, and how more information will be obtained about Sitagliptin's risks and uncertainties (missing information).

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

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

I. The Medicine and What It is used for

Sitagliptin is authorised for adult patients with type 2 diabetes mellitus (see SmPC for the full indication). It contains Sitagliptin as the active substance and it is given orally.

II. Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

Important risks of Sitagliptin, together with measures to minimise such risks and the proposed studies for learning more about Sitagliptin's risks, if any, 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 Sitagliptin is not yet available, it is listed under ‘missing information’ below.

II.A List of Important Risks and Missing Information

Important risks of Sitagliptin 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 Sitagliptin. 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 7: Summary of Safety Concerns

Summary of safety concerns	
Important identified risks	• None
Important potential risks	• Pancreatic cancer
Missing information	• Exposure during pregnancy and lactation

II.B Summary of Important Risks

Table 8: Summary of Pharmacovigilance Activities and Additional Risk Minimisation Activities by Safety Concern

Important potential risk: Pancreatic cancer	
Risk minimisation measures	Routine risk minimisation measures None Additional risk minimisation measures None
Missing information: Exposure during pregnancy and lactation	
Risk minimisation measures	Routine risk minimisation measures Risk is listed in SmPC section 4.6. Described in PL section 2. Additional risk minimisation measures None

II.C Post-Authorisation Development Plan

II.C.1 Studies Which Are Conditions of the Marketing Authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Sitagliptin.

II.C.2 Other Studies in Post-Authorisation Development Plan

There are no studies required for Sitagliptin.