Part VI Summary of the risk management plan for Sitagliptin

This is a summary of risk management plan (RMP) for Sitagliptin 25mg & 50mg & 100mg filmcoated tablets.
The RMP details important risks of Sitagliptin 25mg & 50mg & 100mg film-coated tablets, how these risks can be minimised, and how more information will be obtained about Sitagliptin 25mg & 50mg & 100mg film-coated tablets risks and uncertainties (missing information).
Sitagliptin 25mg & 50mg & 100mg film-coated tablets summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Sitagliptin 25mg & 50mg & 100mg film-coated tablets should be used.

I. The medicine and what it is used for
Sitagliptin 25mg & 50mg & 100mg film-coated tablets is authorised for the management of glycemic control in type 2 diabetes mellitus along, with diet and exercise. (SmPC)**.** It contains Sitagliptin as the active substance and it is given by oral route.

II. Risks associated with the medicine and activities to minimise or further characterise the risks
Important risks of Sitagliptin 25mg & 50mg & 100mg film-coated tablets together with measures to minimise such 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.

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.
Together, these measures constitute routine risk minimisation measures.
In the case of Sitagliptin 25mg & 50mg & 100mg film-coated tablets, these measures are supplemented with additional risk minimization measures for the risks below:

II.A List of important risks and missing information
Important risks of Sitagliptin 25mg & 50mg & 100mg film-coated tablets are risks that need special risk management activities to further investigate or minimise 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 Sitagliptin 25mg & 50mg & 100mg film-coated tablets. 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 03. Summary of Safety Concerns

Important Identified Risks	• None
Important Potential Risks	• None
Missing Information	• None

II.B Summry 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 which are conditions of the marketing authorisation or specific obligation of Sitagliptin 25mg & 50mg & 100mg film-coated tablets.