13 Part VI: Summary of the risk management plan (RMP) Sitagliptin hydrochloride, 25 mg, 50 mg and 100 mg, Film-coated tablets

This is a summary of the RMP for sitagliptin hydrochloride, 25 mg, 50 mg and 100 mg, film-coated tablets. The RMP details important risks of sitagliptin hydrochloride film-coated tablets, how these risks can be minimized, and how more information will be obtained about sitagliptin hydrochloride film-coated tablet's risks and uncertainties (missing information).

Sitagliptin hydrochloride film-coated tablet's summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals (HCPs) and patients on how sitagliptin hydrochloride film-coated tablets should be used.

Important new concerns or changes to the current ones will be included in updates of sitagliptin hydrochloride film-coated tablet's RMP.

13.1 Part VI: I. The medicine and what it is used for

For adult patients with type 2 diabetes mellitus, sitagliptin hydrochloride is indicated to improve glycemic control:

As monotherapy

- In patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance.

As dual oral therapy in combination with

- Metformin when diet and exercise plus metformin alone do not provide adequate glycemic control.
- A sulphonylurea when diet and exercise plus maximal tolerated dose of a sulphonylurea alone do not provide adequate glycemic control and when metformin is inappropriate due to contraindications or intolerance.
- A peroxisome proliferator-activated receptor gamma (PPARγ) agonist (i.e. a thiazolidinedione) when use of a PPARγ agonist is appropriate and when diet and exercise plus the PPARγ agonist alone do not provide adequate glycemic control.

As triple oral therapy in combination with

- A sulphonylurea and metformin when diet and exercise plus dual therapy with these medicinal products do not provide adequate glycemic control.
- A PPARγ agonist and metformin when use of a PPARγ agonist is appropriate and when diet and exercise plus dual therapy with these medicinal products do not provide adequate glycemic control.

Sitagliptin hydrochloride is also indicated as add-on to insulin (with or without metformin) when diet and exercise plus stable dose of insulin do not provide adequate glycemic control.

It contains sitagliptin hydrochloride as the active substance and is given orally in the form of film-coated tablets (25 mg, 50 mg and 100 mg).

13.2 Part VI: II. Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of sitagliptin hydrochloride film-coated tablets, together with measures to minimize such 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 PL and SmPC addressed to patients and HCPs;
- 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, including periodic safety update report (PSUR) assessment, if applicable, so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance (PhV) activities*.

If important information that may affect the safe use of sitagliptin hydrochloride film-coated tablets is not yet available, it is listed under 'missing information' below.

13.2.1 Part VI – II.A: List of important risks and missing information

Important risks of sitagliptin hydrochloride film-coated tablets 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 sitagliptin hydrochloride 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 13-1 List of important risks and missing information

List of important risks and missing information	
Important identified risks	None
Important potential risks	Pancreatic cancer
Missing information	Exposure during pregnancy and lactation

13.2.2 Part VI – II.B: Summary of important risks

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

13.2.3 Part VI – II.C: Post-authorization development plan

13.2.3.1 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 sitagliptin hydrochloride film-coated tablets.

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

There are no studies required for sitagliptin hydrochloride film-coated tablets.