Part VI: Summary of the risk management plan (RMP) – Sitagliptin + Metformin hydrochloride, 50 mg + 850 mg and 50 mg + 1000 mg, Film-coated tablets

This is a summary of the RMP for Sitagliptin + Metformin hydrochloride, 50 mg + 850 mg and 50 mg + 1000 mg, film-coated tablets. The RMP details important risks of Sitagliptin + Metformin hydrochloride film-coated tablets, how these risks can be minimized, and how more information will be obtained about Sitagliptin + Metformin hydrochloride film-coated tablets' risks and uncertainties (missing information).

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

Important new concerns or changes to the current ones will be included in updates of the Sitagliptin + Metformin hydrochloride film-coated tablets' RMP.

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

For adult patients with type 2 diabetes mellitus:
Sitagliptin + Metformin hydrochloride is indicated as an adjunct to diet and exercise to improve glycemic control in patients inadequately controlled on their maximal tolerated dose of metformin alone or those already being treated with the combination of sitagliptin and metformin.

Sitagliptin + Metformin hydrochloride is indicated in combination with a sulphonylurea (i.e., triple combination therapy) as an adjunct to diet and exercise in patients inadequately controlled on their maximal tolerated dose of metformin and a sulphonylurea.

Sitagliptin + Metformin hydrochloride is indicated as triple combination therapy with a peroxisome proliferator-activated receptor gamma (PPARγ) agonist (i.e., a thiazolidinedione) as an adjunct to diet and exercise in patients inadequately controlled on their maximal tolerated dose of metformin and a PPARγ agonist.

Sitagliptin + Metformin hydrochloride is also indicated as add-on to insulin (i.e., triple combination therapy) as an adjunct to diet and exercise to improve glycemic control in patients when stable dose of insulin and metformin alone do not provide adequate glycemic control

It contains Sitagliptin + Metformin hydrochloride as active substance and is given orally as film-coated tablets (50 mg + 850 mg and 50 mg + 1000 mg).

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

Important risks of Sitagliptin + Metformin 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, 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 + Metformin hydrochloride film-coated tablets is not yet available, it is listed under 'missing information' below.

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

Important risks of Sitagliptin + Metformin 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 + Metformin 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	Lactic acidosis
Important potential risks	Pancreatic cancer
Missing information	Exposure during pregnancy and lactation

Part VI – II.B: Summary of important risks

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

Part VI – 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 Sitagliptin + Metformin hydrochloride film-coated tablets.

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

There are no studies required for Sitagliptin + Metformin hydrochloride film-coated tablets.