Part VI: Summary of the risk management plan

Summary of risk management plan for Sitagliptin and Metformin hydrochloride 50mg/850mg & 50mg/1000mg film-coated tablets (Sitagliptin and Metformin hydrochloride)

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

Sitagliptin and Metformin hydrochloride´s Summary of Product Characteristics (SmPC) and its Package Leaflet (PL) give essential information to healthcare professionals and patients on how Sitagliptin and Metformin hydrochloride should be used.

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

I. The medicine and what it is used for

Sitagliptin and Metformin hydrochloride tablets are authorised for adult patients with type 2 diabetes mellitus:

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

It contains sitagliptin and metformin hydrochloride as active ingredients and it is given by oral route of administration.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Sitagliptin and Metformin hydrochloride, 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.

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 and Metformin hydrochloride is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Sitagliptin and Metformin hydrochloride 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 and Metformin hydrochloride. 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);

Summary of safety concerns	
Important identified risks	• Lactic acidosis
Important potential risks	• Pancreatic cancer
Missing information	• Exposure during pregnancy and lactation

II.B Summary of important risks

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

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 and Metformin hydrochloride.

II.C.2 other studies in post-authorisation development plan

There are no studies required for Sitagliptin and Metformin hydrochloride.