PART VI - Summary of the risk management plan

This is a summary of risk management plan (RMP) for Sitagliptin Metformin Zentiva/Jamesi.

The RMP details important risks of Sitagliptin Metformin Zentiva/Jamesi, how these risks can be minimised, and how more information will be obtained about Sitagliptin Metformin Zentiva/Jamesi´s risks and uncertainties (missing information).

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

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

I. The medicine and what it is used for

Sitagliptin Metformin Zentiva/Jamesi is authorized for the treatment of adult patients with type 2 diabetes mellitus (see SmPC for the full indication). It contains Sitagliptin hydrochloride and Metformin hydrochloride 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 Metformin Zentiva/Jamesi together with measures to minimise such risks are outlined below.

•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, including PSUR assessment, 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 Zentiva/Jamesi is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Sitagliptin Metformin Zentiva/Jamesi 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 Metformin Zentiva/Jamesi.

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)

Tabla 01. Summary of Safety Concerns

Important Identified Risks	- Lactic acidosis (related to the metformin component)
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 the reference medicinal product.

Table 02. Summary of important risks

Important Identified Risk: Lactic acidosis (related to the metformin component)	
Risk minimisation measures	Routine risk minimisation measures SmPC Sections 4.3, 4.4, 4.5, 4.9. PL Section 4. Additional risk minimisation measures NA
Additional pharmacovigilance activities	NA
Important Potential risk: Pancreatic cancer	
Risk minimisation measures	Routine risk minimisation measures SmPC Section: NA PL Section: NA Additional risk minimisation measures NA
Additional pharmacovigilance activities	NA
Missing information: Exposure during pregnancy and lactation	
Risk minimisation measures	Routine risk minimisation measures SmPC Sections: 4.6. PL Section: 2. Additional risk minimisation measures NA

Additional pharmacovigilance activities	NA

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorization

There are no studies which are conditions of the marketing authorisation or specific obligation of Sitagliptin Metformin Zentiva/Jamesi.

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

There are no studies required for Sitagliptin Metformin Zentiva/Jamesi.