Part VI: Summary of the Risk Management Plan

As the safety concerns and their management are identical for all products covered by this RMP, the information in Part VI is presented only once together for all products.

Summary of risk management plan for Metformin+Sitagliptin Zentiva k.s. and Jamesi Novum (sitagliptin phosphate + metformin hydrochloride)
This is a summary of the risk management plan (RMP) for Metformin+Sitagliptin Zentiva k.s. and Jamesi Novum. The RMP details important risks of Metformin+Sitagliptin Zentiva k.s. and Jamesi Novum and how more information will be obtained about Metformin+Sitagliptin Zentiva k.s. and Jamesi Novum's risks and uncertainties (missing information).
Metformin+Sitagliptin Zentiva k.s. and Jamesi Novum's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Metformin+Sitagliptin Zentiva k.s. and Jamesi Novum should be used.

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

I. The medicine and what it is used for

Metformin+Sitagliptin Zentiva k.s. and Jamesi Novum is authorised for adult patients with type 2 diabetes mellitus:

- 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
- 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
- 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
- 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

Refer to SmPC for the full indication.

It contains sitagliptin phosphate + metformin hydrochloride as the active substance 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 Metformin+Sitagliptin Zentiva k.s. and Jamesi Novum, together with measures to minimise such risks and the proposed studies for learning more about Metformin+Sitagliptin Zentiva k.s. and Jamesi Novum's 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 Metformin+Sitagliptin Zentiva k.s. and Jamesi Novum is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Metformin+Sitagliptin Zentiva k.s. and Jamesi Novum are risks that need special risk management activities to further investigate or minimise 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 Metformin+Sitagliptin Zentiva k.s. and Jamesi Novum. 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).

List of important risks and missing information	
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 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 Metformin+Sitagliptin Zentiva k.s. and Jamesi Novum.

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

There are no studies required for Metformin+Sitagliptin Zentiva k.s. and Jamesi Novum.