Summary of risk management plan for Sitagliptin/Metformin hydrochloride SUN (sitagliptin fumarate and metformin hydrochloride)

This is a summary of the risk management plan (RMP) for "Sitagliptin/Metformin hydrochloride SUN". The RMP details important risks of "Sitagliptin/Metformin hydrochloride SUN", how these risks can be minimised, and how more information will be obtained about "Sitagliptin/Metformin hydrochloride SUN" risks and uncertainties (missing information).

"Sitagliptin/Metformin hydrochloride SUN" summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how "Sitagliptin/Metformin hydrochloride SUN " should be used.

This summary of the RMP for "Sitagliptin/Metformin hydrochloride SUN" should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR)

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

I. The medicine and what it is used for

"Sitagliptin/Metformin hydrochloride SUN" is indicated for adult patients with type 2 diabetes mellitus:

- Sitagliptin/Metformin hydrochloride SUN 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/Metformin hydrochloride SUN 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 SUN 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 SUN 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 fumarate equivalent and metformin hydrochloride as the active substance and it is given orally.

Further information about the evaluation of "Sitagliptin/Metformin hydrochloride SUN"'s benefits can be found in "Sitagliptin/Metformin hydrochloride SUN 's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage https://www.ema.europa.eu/en/medicines/human/EPAR/sitagliptin-metformin-hydrochloride-sun.

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

Important risks of "Sitagliptin/Metformin hydrochloride SUN", together with measures to minimise such risks and the proposed studies for learning more about "Sitagliptin/Metformin hydrochloride SUN" 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/Metformin hydrochloride SUN" 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 hydrochloride SUN" 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 hydrochloride SUN". 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 Sitagliptin/Metformin hydrochloride SUN.

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

There are no studies required for Sitagliptin/Metformin hydrochloride SUN.