Summary of risk management plan for Sitagliptin SUN 25, 50 and 100 mg film-coated tablets

(sitagliptin phosphate monohydrate)

This is a summary of the risk management plan (RMP) for Sitagliptin SUN 25, 50 and 100 mg film-coated tablets. The RMP details important risks of Sitagliptin SUN 25, 50 and 100 mg film-coated tablets, how these risks can be minimised, and how more information will be obtained about Sitagliptin SUN 25, 50 and 100 mg film-coated tablets risks and uncertainties (missing information).

Sitagliptin SUN 25, 50 and 100 mg film-coated tablets summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Sitagliptin SUN 25, 50 and 100 mg film-coated tablets should be used.

Important new concerns or changes to the current ones will be included in updates of Sitagliptin SUN 25, 50 and 100 mg film-coated tablets' RMP.

I. The medicine and what it is used for

Sitagliptin SUN 25, 50 and 100 mg film-coated tablets is indicated for adult patients with type 2 diabetes mellitus to improve glycaemic control. It contains sitagliptin phosphate monohydrate as the active substance and it is given orally.

Further information about the evaluation of Sitagliptin SUN 25, 50 and 100 mg film-coated tablets's benefits can be found in Sitagliptin SUN 25, 50 and 100 mg film-coated tablets'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-sun.

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

Important risks of Sitagliptin SUN 25, 50 and 100 mg film-coated tablets, together with measures to minimise such risks and the proposed studies for learning more about Sitagliptin SUN 25, 50 and 100 mg film-coated tablets'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, 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 SUN 25, 50 and 100 mg film-coated tablets is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Sitagliptin SUN 25, 50 and 100 mg film-coated tablets 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 SUN 25, 50 and 100 mg 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.

List of important risks and missing information	
Important identified risks	• **None**
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 of Sitagliptin is aligned to the list of safety concerns per the last approved RMP (Version 0.2 dated 23.12.2019) available on CMDh site for Sitagliptin (Maysiglu, Sitagliptin Krka, Sitagavia, Sitagliptin TAD).[2]

II.C Post-authorisation development plan

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

None proposed.

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

None.