

Part VI: Summary of the risk management plan

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

Sitagliptin Pharmazac summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Sitagliptin Pharmazac should be used. This summary of the RMP for Sitagliptin Pharmazac 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 EPAR.

Important new concerns or changes to the current ones will be included in updates of Sitagliptin Pharmazac RMP.

I. The medicine and what it is used for

For adult patients with type 2 diabetes mellitus, Sitagliptin Pharmazac is indicated to improve glycaemic control: as monotherapy:

- in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance.

as dual oral therapy in combination with:

- metformin when diet and exercise plus metformin alone do not provide adequate glycaemic control.
- a sulphonylurea when diet and exercise plus maximal tolerated dose of a sulphonylurea alone do not provide adequate glycaemic control and when metformin is inappropriate due to contraindications or intolerance.
- a peroxisome proliferator-activated receptor gamma (PPAR γ) agonist (i.e. a thiazolidinedione) when use of a PPAR γ agonist is appropriate and when diet and exercise plus the PPAR γ agonist alone do not provide adequate glycaemic control.

as triple oral therapy in combination with:

- a sulphonylurea and metformin when diet and exercise plus dual therapy with these medicinal products do not provide adequate glycaemic control.
- a PPAR γ agonist and metformin when use of a PPAR γ agonist is appropriate and when diet and exercise plus dual therapy with these medicinal products do not provide adequate glycaemic control.

Sitagliptin Pharmazac is also indicated as add-on to insulin (with or without metformin) when diet and exercise plus stable dose of insulin do not provide adequate glycaemic control.

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

Important risks of Sitagliptin Pharmazac film-coated tablets together with measures to minimise such risks and the proposed studies for learning more about Sitagliptin Pharmazac film-coated tablets 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, such as warnings, precautions, and advice on correct use;
- Important advice on the medicine's packaging;
- The authorised pack size — specific number of tablets 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 public (with prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

If important information that may affect the safe use of Sitagliptin Pharmazac 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 Pharmazac 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 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 Sitagliptin Pharmazac 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 (e.g. on the long-term use of the medicine).

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 is aligned to the reference medicinal product.

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 Pharmazac.

Other studies in post-authorisation development plan