

Part VI: Summary of the risk management plan

Summary of risk management plan for Sitagliptin / Dapagliflozin 100 mg / 10 mg film-coated tablets film-coated tablets (sitagliptin / dapagliflozin)

This is a summary of the risk management plan (RMP) for Sitagliptin / Dapagliflozin 100 mg /10 mg film-coated tablets (sitagliptin / dapagliflozin). The RMP details important risks of Sitagliptin / Dapagliflozin, 100 mg // 0 mg film-coated tablets, (sitagliptin / dapagliflozin) how these risks can be minimised, and how more information will be obtained about Sitagliptin / Dapagliflozin 100 mg /10 mg film-coated tablets (sitagliptin / dapagliflozin)'s risks and uncertainties (missing information).

Sitagliptin / Dapagliflozin 100 mg /10 mg film-coated tablets (sitagliptin / dapagliflozin)'s summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Sitagliptin / Dapagliflozin 100 mg /10 mg film-coated tablets (sitagliptin / dapagliflozin) should be used.

Important new concerns or changes to the current ones will be included in updates of Sitagliptin / Dapagliflozin 100 mg /10 mg film-coated tablets' RMP.

I. The medicine and what it is used for

Sitagliptin / Dapagliflozin 100 mg /10 mg film-coated tablets (sitagliptin / dapagliflozin) are indicated as an adjunct to diet and exercise in adult patients aged 18 years and older with type 2 diabetes mellitus:

- to improve glycaemic control when metformin and sitagliptin do not provide adequate glycaemic control,

- when already being treated with the free combination of sitagliptin and dapagliflozin given concurrently, at the same dose level as in the fixed dose combination, but as separate products.

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

Important risks of Sitagliptin / Dapagliflozin 100 mg /10 mg film-coated tablets, together with measures to minimise such risks and the proposed studies for learning more about Sitagliptin / Dapagliflozin 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, 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 / Dapagliflozin, 100 mg /10 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 / Dapagliflozin, 100 mg /10 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 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 / Dapagliflozin 100 mg /10 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 (e.g. on the long-term use of the medicine).

Summary of safety concerns	
Important identified risks	Diabetic Ketoacidosis including events with atypical presentation
Important potential risks	Pancreatic cancer Bladder cancer Breast cancer Prostate 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. The reference product for Sitagliptin is Januvia film-coated tablets and for Dapagliflozin Forxiga film-coated tablet.

II.C Post-authorisation development plan

Not applicable, since there are no studies which are conditions of the marketing authorisation or specific obligation of Sitagliptin / Dapagliflozin film — coated tablets.