

Part VI: Summary of the risk management plan

Summary of risk management plan for Zinatis (sitagliptin/dapagliflozin)

This is a summary of the risk management plan (RMP) for Zinatis. The RMP details important risks of Zinatis, how these risks can be minimised, and how more information will be obtained about Zinatis's risks and uncertainties (missing information).

Zinatis's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Zinatis should be used.

Important new concerns or changes to the current ones will be included in updates of Zinatis's RMP.

I. The medicine and what it is used for

Zinatis, fixed dose combination of sitagliptin and dapagliflozin, is indicated as an adjunct to diet and physical 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, and 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. It contains sitagliptin/dapagliflozin as the active substances, and it is given by oral route.

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

Important risks of Zinatis, together with measures to minimise such risks and the proposed studies for learning more about Zinatis'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 Zinatis is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Zinatis 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 Zinatis. 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	• Bladder cancer • Breast cancer • Pancreatic 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 products.

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 Zinatis.

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

There are no studies required for Zinatis.