

Part VI: Summary of the risk management plan

Summary of risk management plan for FORDIABIK (sitagliptin 50 mg/100 mg film-coated tablets)

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

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

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

I. The medicine and what it is used for

For adult patients with type 2 diabetes mellitus, Fordiabik 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.

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.

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 hydrochloride 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.

It contains sitagliptin hydrochloride as the active substance, 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 Fordiabik, together with measures to minimise such risks and the proposed studies for learning more about Fordiabik '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 Fordiabik is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Fordiabik 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 Fordiabik. 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 authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Fordiabik.

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

There are no studies required for Fordiabik.