Part VI: Summary of the risk management plan

Summary of risk management plan for Frekidir25, 50, 100 mg film-coated tablets

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

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

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

I. The medicine and what it is used for

Frekidir 25, 50, 100 mg film-coated tablets is indicated in adult patients with type 2 diabetes mellitus, 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 (PPARγ) agonist (i.e. a thiazolidinedione) when use of a PPARγ agonist is appropriate and when diet and exercise plus the PPARγ 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 PPARγ agonist and metformin when use of a PPARγ agonist is appropriate and when diet and exercise plus dual therapy with these medicinal products do not provide adequate glycaemic control.

Frekidir 25, 50, 100 mg film-coated tablets 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.

Frekidir 25, 50, 100 mg film-coated tablets contain sitagliptin as the active substance and it is given orally.

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

Important risks of Frekidir 25, 50, 100 mg film-coated tablets, together with measures to minimise such risks and the proposed studies for learning more about Frekidir 25, 50, 100 mg film-coated tablets risks, are outlined below.

Measures to minimise the risks Frekidir 25, 50, 100 mg film-coated tablets include:

- 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 necessary. These measures constitute *routine pharmacovigilance activities*.

If important information that may affect the safe use of Frekidir 25, 50, 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 Frekidir 25, 50, 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 Frekidir 25, 50, 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 (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 Frekidir 25, 50, 100 mg film-coated tablets.

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

There are no studies required for Frekidir 25, 50, 100 mg film-coated tablets.