Part VI: Summary of the risk management plan

Summary of risk management plan for Vildagliptin Accord 50 mg tablets & Vildagliptin 50 mg tablets (Vildagliptin)

This is a summary of the risk management plan (RMP) for Vildagliptin Accord 50 mg tablets and Vildagliptin 50 mg tablets. The RMP details important risks of Vildagliptin Accord 50 mg tablets and Vildagliptin 50 mg tablets, how these risks can be minimised, and how more information will be obtained about Vildagliptin Accord 50 mg tablets and Vildagliptin 50 mg tablets' risks and uncertainties (missing information).

Vildagliptin Accord 50 mg tablets and Vildagliptin 50 mg tablet's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Vildagliptin Accord 50 mg tablets and Vildagliptin 50 mg tablets should be used.

Important new concerns or changes to the current ones will be included in updates of Vildagliptin Accord 50 mg tablets and Vildagliptin 50 mg tablets' RMP.

I. The medicine and what it is used for

Vildagliptin Accord 50 mg tablets indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus:

as monotherapy

- in patients.
- in whom metformin is inappropriate due to contraindications or intolerance.

in combination with

- other medicinal products for the treatment of diabetes, including insulin, when these do not provide adequate glycaemic control.

Vildagliptin 50 mg tablets is indicated in the treatment of type 2 diabetes mellitus in adults:

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, in patients with insufficient glycaemic control despite maximal tolerated dose of monotherapy with metformin,
- a sulphonylurea, in patients with insufficient glycaemic control despite maximal tolerated dose of a sulphonylurea and for whom metformin is inappropriate due to contraindications or intolerance,
- a thiazolidinedione, in patients with insufficient glycaemic control and for whom the use of a thiazolidinedione is appropriate.

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.
- Vildagliptin is also indicated for use in combination with insulin (with or without metformin) when diet and exercise plus a stable dose of insulin do not provide adequate glycaemic control.

They contain vildagliptin 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 Vildagliptin Accord 50 mg tablets and Vildagliptin 50 mg tablets together with measures to minimise such risks and the proposed studies for learning more about Vildagliptin Accord 50 mg 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;
- 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*.

II.A List of important risks and missing information

Important risks of Vildagliptin Accord 50 mg tablets and Vildagliptin 50 mg 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 Vildagliptin Accord 50 mg tablets and Vildagliptin 50 mg 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).

Important identified risk (s)	• Drug-induced liver injury (DILI) • Acute pancreatitis
Important potential risk (s)	• Muscle events/myopathy/rhabdomyolysis, in particular with current statin use (events of myalgia excluded)
Missing information	• None

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 Vildagliptin Accord 50 mg tablets and Vildagliptin 50 mg tablets.

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

There are no studies required for Vildagliptin Accord 50 mg tablets and Vildagliptin 50 mg tablets.