Part VI: Summary of the risk management plan

Summary of risk management plan for Vildagliptin Accord (Vildagliptin)

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

Vildagliptin Accord 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 should be used.

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

I. The medicine and what it is used for

Vildagliptin Accord 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 and dual oral therapy in combination with metformin, sulphonylurea and thiazolidinedione in patients with insufficient glycaemic control and as triple oral therapy in combination with sulphonylurea and metformin when diet and exercise plus dual therapy with these medicinal products do not provide adequate glycaemic control. Vildagliptin is also indication 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

These 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 together with measures to minimise such risks and the proposed studies for learning more about Vildagliptin Accord 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.

If important information that may affect the safe use of Vildagliptin Accord is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Vildagliptin Accord 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. 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)	• Transaminase elevations and Drug-induced liver injury (DILI) • Angioedema • Acute pancreatitis • Skin lesions • Hypoglycaemia
Important potential risk (s)	• Serious infections • Cardiac events in CHF (NYHA Functional Class

	III) patients • Muscle events /myopathy /rhabdomyolysis, in particular with current statin use • Neuropsychiatric events • Breast cancer • Pancreatic cancer
Missing information	• Patients with severe hepatic impairment • Patients with compromised cardiac function (NYHA functional class IV) • Pregnancy • Gender incidence/frequency differences

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.

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

There are no studies required for Vildagliptin Accord.