Part VI: Summary of the risk management plan

Summary of risk management plan for [VILDAGLIPTIN] 50 MG TABLETS.

This is a summary of the risk management plan (RMP) for [VILDAGLIPTIN] 50 MG TABLETS, how these risks can be minimised, and how more information will be obtained about [VILDAGLIPTIN] 50 MG TABLETS risks and uncertainties (missing information).
[VILDAGLIPTIN] 50 MG TABLETS summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how [VILDAGLIPTIN] 50 MG TABLETS should be used.

I. The medicine and what it is used for

The active substance of [VILDAGLIPTIN] 50 MG TABLETS, belongs to a group of medicines called "oral antidiabetics".

[VILDAGLIPTIN] 50 MG TABLETS is used to treat adult patients with type 2 diabetes. It is used when diabetes cannot be controlled by diet and exercise alone. It helps to control the level of sugar in the blood. Your doctor will prescribe [VILDAGLIPTIN] 50 MG TABLETS either alone or together with certain other antidiabetic medicines which you will already be taking, if these have not proved sufficiently effective to control diabetes.

Type 2 diabetes develops if the body does not make enough insulin or if the insulin that the body makes does not work as well as it should. It can also develop if the body produces too much glucagon.

Insulin is a substance which helps to lower the level of sugar in the blood, especially after meals. Glucagon is a substance which triggers the production of sugar by the liver, causing the blood sugar level to rise. The pancreas makes both of these substances.

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

Important risks of [VILDAGLIPTIN] 50 MG TABLETS, together with measures to minimise such risks and the proposed studies for learning more about [VILDAGLIPTIN] 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.
If important information that may affect the safe use of [VILDAGLIPTIN] 50 MG TABLETS is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of [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 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 [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);

Summary of safety concerns	
Important identified risks	• Drug-induced liver injury • Angioedema • Acute pancreatitis • Exfoliative and bullous skin lesions, including bullous pemphigoid • Hypoglycaemia
Important potential risks	• Cardiac events in CHF (NYHA Functional Class III) patients • Muscle events/myopathy/rhabdomyolysis with current statin use
Missing information	• Use in patients with severe hepatic impairment • Use in patients with compromised cardiac function (NYHA functional class IV) • Use in pregnancy and lactation • Use in paediatric population

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] 50 MG TABLETS.

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

There are no studies required for [VILDAGLIPTIN] 50 MG TABLETS.