Part VI: Summary of the risk management plan

Summary of risk management plan for Vildagliptin tablets

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

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

I. The medicine and what it is used for

Vildagliptin tablets are authorised for the treatment of type 2 diabetes mellitus in adults as monotherapy, as dual oral therapy in combination with metformin or sulphonylurea or thiazolidinedione and as triple oral therapy in combination with a sulphonylurea and metformin.

Vildagliptin is also indicated for use in combination with insulin (with or without metformin).

See SmPC for the full indication.

Vildagliptin tablets contain vildagliptin as the active substance and it is given by mouth. Vildagliptin tablets are available in strength of 50 mg.

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

Important risks of Vildagliptin tablets, together with measures to minimise such risks and the proposed studies for learning more about vildagliptin'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.

If important information that may affect the safe use of vildagliptin is not yet available, it is listed under ‘missing information’ below.

II.A List of important risks and missing information

Important risks of Vildagliptin 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 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	• Transaminase elevations and drug induced liver injury (DILI) • Angioedema • Acute Pancreatitis • Skin lesions • Hypoglycaemia
Important potential risks	• 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.

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

There are no studies required for Vildagliptin.