Part VI: Summary of the risk management plan

Summary of risk management plan for Vildagliptin/Metformin HCL 50/850 mg, 50/1000 mg film coated tablets.

This is a summary of the risk management plan (RMP) for Vildagliptin/Metformin HCL 50/850 mg, 50/1000 mg film coated tablets. The RMP details important risks of Vildagliptin/Metformin HCL 50/850 mg, 50/1000 mg film coated tablets, how these risks can be minimised, and how more information will be obtained about Vildagliptin/Metformin HCL 50/850 mg, 50/1000 mg film coated tablets risks and uncertainties missing information.

Vildagliptin/Metformin HCL 50/850 mg, 50/1000 mg film coated tablets summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Vildagliptin/Metformin HCL 50/850 mg, 50/1000 mg film coated tablets should be used.

I. The medicine and what it is used for

Vildagliptin/Metformin HCL 50/850 mg, 50/1000 mg film coated tablets are authorised for the treatment of type 2 diabetes mellitus.

Vildagliptin/Metformin is indicated in the treatment of adult patients who are unable to achieve sufficient glycaemic control at their maximally tolerated dose of oral metformin alone or who are already treated with the combination of vildagliptin and metformin as separate tablets.

Vildagliptin/Metformin is indicated in combination with a sulphonylurea (i.e. triple combination therapy) as an adjunct to diet and exercise in adult patients inadequately controlled with metformin and a sulphonylurea.

Vildagliptin/Metformin is indicated in triple combination therapy with insulin as an adjunct to diet and exercise to improve glycaemic control in adult patients when insulin at a stable dose and metformin alone do not provide adequate glycaemic control.

(see SmPC for the full indication). It contains Vildagliptin/Metformin as the active substance and it is given by mouth.

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

Important risks of Vildagliptin/Metformin HCL 50/850 mg, 50/1000 mg film coated tablets together with measures to minimise such risks and the proposed studies for learning more about Vildagliptin/Metformin HCL 50/850 mg, 50/1000 mg film coated 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 the case of Vildagliptin/Metformin HCL 50/850 mg, 50/1000 mg film coated tablets these measures are supplemented with *additional risk minimisation measures* mentioned under relevant important risks, below.

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/Metformin HCL 50/850 mg, 50/1000 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 Vildagliptin/Metformin HCL 50/850 mg, 50/1000 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 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/Metformin HCL 50/850 mg, 50/1000 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	• Drug-induced liver injury (DILI) • Acute pancreatitis • Lactic acidosis

List of important risks and missing information	
Important potential risks	• 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/Metformin.

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

There are no studies required for Vildagliptin/Metformin.