Part VI: Summary of the risk management plan

Summary of risk management plan for Vildagliptin and Metformin hydrochloride 50mg/850mg film coated tablets and Vildagliptin and Metformin hydrochloride 50mg/1000mg film-coated tablets (Vildagliptin and Metformin)

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

Vildagliptin and Metformin´s Summary of Product Characteristics (SmPC) and its Package Leaflet (PL) give essential information to healthcare professionals and patients on how the tablets should be used.

Important new concerns or changes to the current ones will be included in updates of this Vildagliptin and Metformin RMP.

I. The medicine and what it is used for

Vildagliptin and Metformin is authorised for:

the treatment of type 2 diabetes mellitus:

- 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.

- 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.

- 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.

The tablets contain Vildagliptin and Metformin hydrochloride as the active substances and are given by oral route of administration.

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

Important risks of Vildagliptin and Metformin, together with measures to minimise such 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 and Metformin 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 and Metformin. 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 • Acute pancreatitis • Lactic acidosis
Important potential risks	• Muscle events/myopathy/rhabdomyolysis, in particular with current statin use (events of myopathy excluded).
Missing information	• None

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to that of 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 and Metformin.

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

There are no studies required for Vildagliptin and Metformin.