Part VI: Summary of the risk management plan

Summary of risk management plan for **[Vildagliptin/Metformin] 50mg/850mg film-coated tablets, [Vildagliptin/Metformin] 50mg/100mg film-coated tablets**

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

[Vildagliptin/Metformin]'s Summary of Product Characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how [Vildagliptin/Metformin] should be used.

This summary of the RMP for [Vildagliptin/Metformin] should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of [Vildagliptin/Metformin]'s RMP.

I. The medicine and what it is used for

[Vildagliptin/Metformin] is authorised for the treatment of adult patients with type 2 diabetes. This type of diabetes is also known as noninsulin-dependent diabetes mellitus.

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. Both insulin and glucagon are made in the pancreas. Insulin helps to lower the level of sugar in the blood, especially after meals. Glucagon triggers the liver to make sugar, causing the blood sugar level to rise.

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

Important risks of [Vildagliptin/Metformin], together with measures to minimise such risks and the proposed studies for learning more about [Vildagliptin/Metformin], 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 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] 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/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	• Transaminase elevation and drug-induced liver injury (DILI) • Angioedema • Acute pancreatitis • Lactic acidosis • Skin Lesions • Hypoglycaemia
Important Potential Risks	• Serious infections • Cardiac events in congestive heart failure (NYHA functional • class III) patients • Muscle events/myopathy/rhabdomyolysis, in particular with • current statin use • Neuropsychiatric events • Breast cancer • Pancreatic cancer
Missing Information	• Gender incidence/frequency differences • Patients with severe hepatic impairment • Patients with compromised cardiac function (NYHA functional • class IV) • Pregnancy

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 authorization

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].