Part VI: Summary of the risk management plan

Summary of risk management plan for Vildagliptin/Metformin 1A Pharma GmbH 50 mg/850 mg – Filmtabletten, Vildagliptin/Metformin 1A Pharma GmbH 50 mg/1000 mg – Filmtabletten, Vildagliptin/Metformin Sandoz GmbH 50 mg/850 mg – Filmtabletten, Vildagliptin/Metformin Sandoz GmbH 50 mg/1000 mg – Filmtabletten (vildagliptin + metformin hydrochloride)

This is a summary of the risk management plan (RMP) for Vildagliptin/Metformin 1A Pharma GmbH 50 mg/850 mg – Filmtabletten, Vildagliptin/Metformin 1A Pharma GmbH 50 mg/1000 mg – Filmtabletten, Vildagliptin/Metformin Sandoz GmbH 50 mg/850 mg – Filmtabletten, Vildagliptin/Metformin Sandoz GmbH 50 mg/1000 mg – Filmtabletten. The RMP details important risks of Vildagliptin/Metformin 1A Pharma GmbH 50 mg/850 mg – Filmtabletten, Vildagliptin/Metformin 1A Pharma GmbH 50 mg/1000 mg – Filmtabletten, Vildagliptin/Metformin Sandoz GmbH 50 mg/850 mg – Filmtabletten, Vildagliptin/Metformin Sandoz GmbH 50 mg/1000 mg – Filmtabletten, how these risks can be minimised, and how more information will be obtained about Vildagliptin/Metformin 1A Pharma GmbH 50 mg/850 mg – Filmtabletten, Vildagliptin/Metformin 1A Pharma GmbH 50 mg/1000 mg – Filmtabletten, Vildagliptin/Metformin Sandoz GmbH 50 mg/850 mg – Filmtabletten, Vildagliptin/Metformin Sandoz GmbH 50 mg/1000 mg – Filmtabletten's risks and uncertainties (missing information).

Vildagliptin/Metformin 1A Pharma GmbH 50 mg/850 mg – Filmtabletten, Vildagliptin/Metformin 1A Pharma GmbH 50 mg/1000 mg – Filmtabletten, Vildagliptin/Metformin Sandoz GmbH 50 mg/850 mg – Filmtabletten, Vildagliptin/Metformin Sandoz GmbH 50 mg/1000 mg – Filmtabletten's summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals (HCPs) and patients on how Vildagliptin/Metformin 1A Pharma GmbH 50 mg/850 mg – Filmtabletten, Vildagliptin/Metformin 1A Pharma GmbH 50 mg/1000 mg – Filmtabletten, Vildagliptin/Metformin Sandoz GmbH 50 mg/850 mg – Filmtabletten, Vildagliptin/Metformin Sandoz GmbH 50 mg/1000 mg – Filmtabletten' should be used.

Important new concerns or changes to the current ones will be included in updates of Vildagliptin/Metformin 1A Pharma GmbH 50 mg/850 mg – Filmtabletten, Vildagliptin/Metformin 1A Pharma GmbH 50 mg/1000 mg – Filmtabletten, Vildagliptin/Metformin Sandoz GmbH 50 mg/850 mg – Filmtabletten, Vildagliptin/Metformin Sandoz GmbH 50 mg/1000 mg – Filmtabletten's RMP.

I. The medicine and what it is used for

Vildagliptin/Metformin 1A Pharma GmbH 50 mg/850 mg – Filmtabletten, Vildagliptin/Metformin 1A Pharma GmbH 50 mg/1000 mg – Filmtabletten, Vildagliptin/Metformin Sandoz GmbH 50 mg/850 mg – Filmtabletten, Vildagliptin/Metformin Sandoz GmbH 50 mg/1000 mg – Filmtabletten are authorised for:

As an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus:

- in patients who are inadequately controlled with metformin hydrochloride alone.
- in patients who are already being treated with the combination of vildagliptin and metformin hydrochloride, as separate tablets.
- in combination with other medicinal products for the treatment of diabetes, including insulin, when these do not provide adequate glycaemic control.

It contains vildagliptin + metformin hydrochloride as the active substance, and it is given by oral route of administration.

II. Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of Vildagliptin/Metformin 1A Pharma GmbH 50 mg/850 mg – Filmtabletten, Vildagliptin/Metformin 1A Pharma GmbH 50 mg/1000 mg – Filmtabletten, Vildagliptin/Metformin Sandoz GmbH 50 mg/850 mg – Filmtabletten, Vildagliptin/Metformin Sandoz GmbH 50 mg/1000 mg – Filmtabletten, together with measures to minimise such risks and the proposed studies for learning more about Vildagliptin/Metformin 1A Pharma GmbH 50 mg/850 mg – Filmtabletten, Vildagliptin/Metformin 1A Pharma GmbH 50 mg/1000 mg – Filmtabletten, Vildagliptin/Metformin Sandoz GmbH 50 mg/850 mg – Filmtabletten, Vildagliptin/Metformin Sandoz GmbH 50 mg/1000 mg – Filmtabletten'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 authorized 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 minimize 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/Metformin 1A Pharma GmbH 50 mg/850 mg – Filmtabletten, Vildagliptin/Metformin 1A Pharma GmbH 50 mg/1000 mg – Filmtabletten, Vildagliptin/Metformin Sandoz GmbH 50 mg/850 mg – Filmtabletten, Vildagliptin/Metformin Sandoz GmbH 50 mg/1000 mg – Filmtabletten 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 1A Pharma GmbH 50 mg/850 mg – Filmtabletten, Vildagliptin/Metformin 1A Pharma GmbH 50 mg/1000 mg – Filmtabletten, Vildagliptin/Metformin Sandoz GmbH 50 mg/850 mg – Filmtabletten, Vildagliptin/Metformin Sandoz GmbH 50 mg/1000 mg – Filmtabletten. 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).

Table 3 – Part VI: List of important risks and missing information

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 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-authorization development plan

II.C.1 Studies which are conditions of the marketing authorization

There are no studies which are conditions of the marketing authorization or specific obligation of Vildagliptin/Metformin 1A Pharma GmbH 50 mg/850 mg – Filmtabletten, Vildagliptin/Metformin 1A Pharma GmbH 50 mg/1000 mg – Filmtabletten, Vildagliptin/Metformin Sandoz GmbH 50 mg/850 mg – Filmtabletten, Vildagliptin/Metformin Sandoz GmbH 50 mg/1000 mg – Filmtabletten.

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

There are no studies required for Vildagliptin/Metformin 1A Pharma GmbH 50 mg/850 mg – Filmtabletten, Vildagliptin/Metformin 1A Pharma GmbH 50 mg/1000 mg – Filmtabletten, Vildagliptin/Metformin Sandoz GmbH 50 mg/850 mg – Filmtabletten, Vildagliptin/Metformin Sandoz GmbH 50 mg/1000 mg – Filmtabletten.