Part VI: Summary of the risk management plan

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

This is a summary of the risk management plan (RMP) for Vildagliptin/Metformin 50 mg/850 mg and 50 mg/1000 mg film-coated tablets. The RMP details important risks of Vildagliptin/Metformin 50 mg/850 mg and 50 mg/1000 mg film-coated tablets, how these risks can be minimised, and how more information will be obtained about Vildagliptin/Metformin50 mg/850 mg and 50 mg/1000 mg film-coated tablets's risks and uncertainties (missing information).

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

I. The medicine and what it is used for

Vildagliptin/Metformin 50 mg/850 mg and 50 mg/1000 mg film-coated tablets is indicated 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 as the active substance and it is 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/Metformin 50 mg/850 mg and 50 mg/1000 mg film-coated tablets, together with measures to minimise such risks and the proposed studies for learning more about

Vildagliptin/Metformin 50 mg/850 mg and 50 mg/1000 mg film-coated tablet'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/Metformin 50 mg/850 mg and 50 mg/1000 mg film-coated tablet 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 50 mg/850 mg and 50 mg/1000 mg film-coated tablet 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/Metformin 50 mg/850 mg and 50 mg/1000 mg film-coated tablet. 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);

Below safety concerns were considered from CMDh list of safety concerns per approved risk management plan (RMP) of active substances per product (Doc. Ref: CMDh/330/2015, Rev.34, June 2021)

List of important risks and missing information

Important Identified Risk	• Transaminase elevations and drug-induced liver injury (DILI) • Angioedema • Acute pancreatitis • Skin lesions • Hypoglycaemia
Important Potential Risk	• Serious Infections • Cardiac events in CHF (NYHA Functional Class III) Patients • Muscle events / Myopathy with and whithout concurrent statin use • Neuropsychiatric events • Breast cancer • Pancreatic cancer
Missing Information	• Gender incidence / frequency differences • Patients with severe hepatic impairment • Patient with compromised cardiac function (NYHA functional class IV) • Pregnancy / Breast feeding

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 50 mg/850 mg and 50 mg/1000 mg film-coated tablet.

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

There are no studies required for Vildagliptin/Metformin 50 mg/850 mg and 50 mg/1000 mg film-coated tablet.