Part VI: Summary of the Risk Management Plan

Summary of the Risk Management Plan for Brand Name® (Vildagliptin/metformin hydrochloride)

This is a summary of the risk management plan (RMP) for Brand Name®. The RMP details important risks of the combination Brand Name®, how these risks can be minimized, and how more information will be obtained about Brand Name®' s risks and uncertainties (missing information). Brand Name® 's Summary of Product Characteristics (SmPC) and its package leaflet provide essential information to healthcare professionals and patients on how Brand Name® should be used.

I. The Medicine and What it is used for

Brand Name® is authorized for the treatment of type II diabetes mellitus and it is given orally.

Vildagliptin/ metformin hydrochloride is indicated in the treatment of type 2 diabetes mellitus:

- Vildagliptin/ metformin hydrochloride 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 hydrochloride 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 hydrochloride 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.

II. Risks Associated with the Medicine and Activities to Minimize or Further Characterize the Risks

Important risks of Brand Name®, together with measures to minimize such risks and the proposed studies for learning more about Brand name's risks, are outlined below.

Measures to minimize 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 minimization measures for the product.

In additional to these measures information about adverse reactions is collected continuously and analysed including Periodic Safety Update Reports (PSUR) assessment so that action can be taken as necessary. These measures constitute routine Pharmacovigilance Activities.

II.A List of Important Risks and Missing Information

Important risks of Brand Name® are risks that need special risk management activities to further investigate or minimize 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 this medicine. *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):

The following table shows the summary of safety concerns of vildagliptin/metformin:

List of important risks and missing information	
Important identified risks	• Transaminase elevations and drug induced liver injury (DILI) • Angioedema • Acute Pancreatitis • Skin lesions • Hypoglycemia • Lactic acidosis
Important potential risks	• Serious Infections • Cardiac events in CHF (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 and Risk Minimization Measures

The safety information in the proposed Product Information is aligned to the reference medicinal product.

II.C Post-Authorization Development Plan

Not applicable.

II.C.1 Studies which are Conditions of the Marketing Authorization

There are no studies which are conditions of the Marketing Authorization (MA) or specific obligation of Brand Name®.

II.C.2 Other Studies in the Post-Authorization Development Plan

There are no are no studies required for Brand Name®.

References

Not applicable.