Part VI: Summary of the Risk Management Plan

Summary of the Risk Management Plan for Gluadda® (vildagliptin)

This is a summary of the risk management plan (RMP) for Gluadda®. The RMP details important risks of Gluadda®, how these risks can be minimized, and how more information will be obtained about Gluadda's risks and uncertainties (missing information).

Gluadda's Reference Safety Information (RSI) and its package leaflet provide essential information to healthcare professionals and patients on how Gluadda® should be used.

Important new concerns or changes to the current ones will be included in updates of Gluadda® RMP.

I. The Medicine and What it is used for

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

Gluadda® is indicated in the treatment of type 2 diabetes mellitus in adults:

As monotherapy:

- in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance.

As dual oral therapy in combination with:

- metformin, in patients with insufficient glycemic control despite maximal tolerated dose of monotherapy with metformin,
- a sulphonylurea, in patients with insufficient glycemic control despite maximal tolerated dose of a sulphonylurea and for whom metformin is inappropriate due to contraindications or intolerance,
- a thiazolidinedione, in patients with insufficient glycemic control and for whom the use of a thiazolidinedione is appropriate.

As triple oral therapy in combination with:

- a sulphonylurea and metformin when diet and exercise plus dual therapy with these medicinal products do not provide adequate glycemic control.

Gluadda® is also indicated for use in combination with insulin (with or without metformin) when diet and exercise plus a stable dose of insulin do not provide adequate glycemic control.

Gluadda® contains vildagliptin as the active substance and it is given by oral route.

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

Important risks of Gluadda®, together with measures to minimize such risks and the proposed studies for learning more about Gluadda'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 RSI 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 addition to these measures, information about adverse reactions is collected continuously and analyzed including the Periodic Safety Update Report (PSUR) assessment so that action can be taken as necessary. These measures constitute the *routine Pharmacovigilance Activities.*

II.A List of Important Risks and Missing Information

Important risks of Gluadda® 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:

Summary of safety concerns	
Important identified risks	• Transaminase elevations and drug induced liver injury (DILI) • Angioedema • Acute Pancreatitis • Skin lesions • Hypoglycemia
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 or specific obligation of Gluadda®.

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

There are no studies required for Gluadda®.