Part VI: Summary of the risk management plan

Summary of risk management plan for Glydapia Plus 5mg/850mg filmdragerade tabletter, Glydapia Plus 5mg/1000mg filmdragerade tabletter (Dapagliflozin/Metformin)

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

Glydapia Plus' summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Glydapia Plus should be used.

Important new concerns or changes to the current ones will be included in updates of Glydapia Plus' RMP.

I. The medicine and what it is used for

Glydapia Plus is authorised in adults for the treatment of type 2 diabetes mellitus as an adjunct to diet and exercise:

- in patients insufficiently controlled on their maximally tolerated dose of metformin alone
- in combination with other medicinal products for the treatment of diabetes in patients insufficiently controlled with metformin and these medicinal products
- in patients already being treated with the combination of dapagliflozin and metformin as separate tablets.

It contains dapagliflozin and metformin as the active substances and it is given orally.

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

Important risks of Glydapia Plus, together with measures to minimise such risks and the proposed studies for learning more about Glydapia Plus' 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.

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 Glydapia Plus are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal products 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 Glydapia Plus. Potential risks are concerns for which an association with the use of these medicines 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 products that is currently missing and needs to be collected (e.g. on the long-term use of the medicines).

List of important risks and missing information	
Important identified risks	• Lactic acidosis (metformin) • Diabetic ketoacidosis including events with atypical presentation (dapagliflozin)
Important potential risks	None
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-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 Glydapia Plus.

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

There are no studies required for Glydapia Plus.