Part VI: Summary of the risk management plan

Summary of risk management plan for Dapagliflozin & Metformin hydrochloride/Genepharm

This is a summary of the risk management plan (RMP) for Dapagliflozin & Metformin hydrochloride/Genepharm. The RMP details important risks of Dapagliflozin & Metformin hydrochloride/Genepharm, how these risks can be minimised, and how more information will be obtained about Dapagliflozin & Metformin hydrochloride/Genepharm's risks and uncertainties (missing information).

Dapagliflozin & Metformin hydrochloride/Genepharm's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Dapagliflozin & Metformin hydrochloride/Genepharm should be used.

Important new concerns or changes to the current ones will be included in updates of Dapagliflozin & Metformin hydrochloride/Genepharm's RMP.

I. The medicine and what it is used for

This medicine contains two different substances called dapagliflozin and metformin. Both belong to a group of medicines called oral anti-diabetics and are medicines taken by mouth for diabetes. Dapagliflozin & Metformin hydrochloride/Genepharm is used for a type of diabetes called "type 2 diabetes" in adult patients (aged 18 years and older) and usually occurs when the patient is older. If a patient has type 2 diabetes, the pancreas does not make enough insulin or the body is not able to use the insulin it produces properly. This leads to a high level of sugar (glucose) in the blood. Dapagliflozin works by removing excess sugar from the body via the urine and lowers the amount of sugar in the blood. Metformin works mainly by inhibiting glucose production in the liver (see SmPC for the full indication). It contains dapagliflozin and metformin as the active substances and it is given by the oral route.

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

Important risks of Dapagliflozin & Metformin hydrochloride/Genepharm, together with measures to minimise such risks and the proposed studies for learning more about Dapagliflozin & Metformin hydrochloride/Genepharm'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.

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.

If important information that may affect the safe use of Dapagliflozin & Metformin hydrochloride/Genepharm is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Dapagliflozin & Metformin hydrochloride/Genepharm 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 Dapagliflozin & Metformin hydrochloride/Genepharm. 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);

List of important risks and missing information	
Important identified risks	• Urinary tract infection (dapagliflozin) • Lactic acidosis (metformin) • Renal impairment (dapagliflozin) • Diabetic Ketoacidosis including events with atypical presentation (dapagliflozin)
Important potential risks	• Liver injury (dapagliflozin) • Bladder cancer (dapagliflozin) • Breast cancer (dapagliflozin) • Prostate cancer (dapagliflozin) • Lower limb amputation (dapagliflozin)
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 Dapagliflozin & Metformin hydrochloride/Genepharm.

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

There are no studies required for Dapagliflozin & Metformin hydrochloride/Genepharm.