Part VI: Summary of the risk management plan

Summary of risk management plan for Dapagliflozin Orion (dapagliflozin)

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

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

Important new concerns or changes to the current ones will be included in updates of Dapagliflozin Orion's RMP.

I. The medicine and what it is used for

Dapagliflozin Orion is authorised for treatment of type 2 diabetes mellitus in adults and children aged 10 years and above as an adjunct to diet and exercise, for treatment of symptomatic chronic heart failure in adults and for treatment of chronic kidney disease in adults (see SmPC for the full indication). It contains dapagliflozin as the active substance and it is given orally.

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

Important risks of Dapagliflozin Orion, together with measures to minimise such risks and the proposed studies for learning more about Dapagliflozin Orion'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 Orion is not yet available, it is listed under ‘missing information’ below.

II.A List of important risks and missing information

Important risks of Dapagliflozin Orion 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. 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	Diabetic ketoacidosis including events with atypical presentation
Important potential risks	Bladder cancer Breast cancer Prostate cancer
Missing information	Use in patients with NYHA class IV Long-term safety in the paediatric population (aged 10 years and above)

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 Orion.

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

There are no studies required for Dapagliflozin Orion.