Part VI: Summary of the Risk Management Plan

Summary of Risk Management Plan for DAPAGLIFLOZIN 5 mg and 10 mg film-coated tablets

This is a summary of the risk management plan (RMP) for DAPAGLIFLOZIN 5 mg and 10 mg film-coated tablets (hereinafter referred to as Dapagliflozin). The RMP details important risks of Dapagliflozin, how these risks can be minimised, and how more information will be obtained about Dapagliflozin's risks and uncertainties (missing information).

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

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

I. The Medicine and What It is used for

Dapagliflozin is authorised for the treatment of insufficiently controlled type 2 diabetes mellitus in adults and children aged 10 years and above as an adjunct to diet and exercise as monotherapy when metformin is considered inappropriate due to intolerance or in addition to other medicinal products for the treatment of type 2 diabetes. Additionally, it is indicated in adults for the treatment of symptomatic chronic heart failure and for the treatment of chronic kidney disease (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, together with measures to minimise such risks and the proposed studies for learning more about Dapagliflozin'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 is not yet available, it is listed under ‘missing information’ below.

II.A List of Important Risks and Missing Information

Important risks of Dapagliflozin 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).

Table 1: Summary of Safety Concerns

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.

II.C.2 Other Studies in Post-Authorisation Development Plan

There are no studies required for Dapagliflozin.