Part VI: Summary of the Risk Management Plan

Summary of the risk management plan for Dapagliflozine Sandoz (dapagliflozin) / Akpanli (dapagliflozin)

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

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

Important new concerns or changes to the current ones will be included in updates of Dapagliflozine Sandoz / Akpanli's RMP.

I. The medicine and what it is used for

Dapagliflozine Sandoz / Akpanli is authorized for:

- Type 2 diabetes mellitus
  - Dapagliflozin is indicated in adults and children aged 10 years and above for the treatment of insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise.
    - It is indicated as monotherapy when metformin is considered inappropriate due to intolerance.
    - It is indicated in addition to other medicinal products for the treatment of type 2 diabetes.
- Heart failure
  - Dapagliflozin is indicated in adults for the treatment of symptomatic chronic heart failure.
- Chronic kidney disease
  - Dapagliflozin is indicated in adults for the treatment of chronic kidney disease.

It contains dapagliflozin as an active substance and it is given by oral administration as film coated tablets (5 mg and 10 mg).

II. Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of Dapagliflozine Sandoz / Akpanli, together with measures to minimize such risks and the proposed studies for learning more about Dapagliflozine Sandoz / Akpanli'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 SmPC 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.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed 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 Dapagliflozine Sandoz / Akpanli is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Dapagliflozine Sandoz / Akpanli are risks that need special risk management activities to further investigate or minimize 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 Dapagliflozine Sandoz / Akpanli. 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 3 Part VI.1 - List of important risks and missing information

List of important risks and missing information	
Important identified risk	Diabetic Ketoacidosis including events with atypical presentation
Important potential risks	Bladder cancer
	Breast cancer
	Prostate cancer
Missing information	Use in patients with New York Heart Association (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-authorization development plan

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 Dapagliflozine Sandoz / Akpanli.

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

There are no studies required for Dapagliflozine Sandoz / Akpanli.