

## **Part VI: Summary of the risk management plan**

### **Summary of risk management plan for dapagliflozin/metformin by Krka (dapagliflozin/metformin)**

This is a summary of the risk management plan (RMP) for dapagliflozin/metformin by Krka. The RMP details important risks of dapagliflozin/metformin by Krka, and how more information will be obtained about dapagliflozin/metformin by Krka's risks and uncertainties (missing information).

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

Important new concerns or changes to the current ones will be included in updates of dapagliflozin/metformin by Krka's RMP.

#### **I. The medicine and what it is used for**

Dapagliflozin/metformin by Krka is indicated in adults for the treatment of type 2 diabetes mellitus as an adjunct to diet and exercise (see SmPC for the full indication). It contains dapagliflozin and metformin 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/metformin by Krka, together with measures to minimise such risks and the proposed studies for learning more about dapagliflozin/metformin by Krka'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*.

**II.A List of important risks and missing information**

Important risks of dapagliflozin/metformin by Krka 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 by Krka. 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 (dapagliflozin) |
|   | Lactic acidosis (metformin)   |
| Important potential risks                       | Bladder cancer (dapagliflozin)  |
|   | Breast cancer (dapagliflozin)   |
|   | Prostate cancer (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 by Krka.

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

There are no studies required for dapagliflozin/metformin by Krka.