

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

Summary of risk management plan for empagliflozin 10 mg & 25 mg film-coated tablets.

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

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

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

Empagliflozin Labiana is authorised for the treatment of Type 2 Diabetes Mellitus, in adults and children aged 10 years and older for the treatment of insufficiently controlled type 2 diabetes mellitus in conjunction with diet and exercise, as monotherapy when metformin is not considered appropriate due to intolerance and added to other medications for the treatment of diabetes.

Empagliflozin Labiana is also indicated for heart failure in adults for the treatment of symptomatic chronic heart failure and for the treatment of chronic kidney disease (CKD). (see SmPC for the full indication).

It contains empagliflozin as the active substance and the presentation is film-coated tablet for oral use, in the strength of 10 mg & 25 mg.

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

Important risks of Empagliflozin Labiana, together with measures to minimise such 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, including Periodic Safety Update Report (PSUR) assessment so that immediate

action can be taken as necessary. These measures constitute routine pharmacovigilance (PhV) activities, part of the pharmacovigilance system based on the current European legislation.

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

Important risks of Empagliflozin Labiana 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 Empagliflozin Labiana. 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 Part VI.II.A List of important risks and missing information

There are no important identified risks or missing information for empagliflozin.

### ***II.B Summary of important risks***

There are no important identified risks or missing information for empagliflozin.

### ***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 Empagliflozin Labiana.

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

There are no studies required for Empagliflozin Labiana.