Part VI: Summary of the risk management plan

This Summary of the risk management plan is applicable to Empaglifozin Devatis 10 mg & 25 mg filmdragerade tabletter.

Summary of risk management plan for Empaglifozin Devatis 10 mg & 25 mg filmdragerade tabletter (Empaglifozin)

This is a summary of the risk management plan (RMP) for *Empaglifozin Devatis 10 mg & 25 mg filmdragerade tabletter*. The RMP details important risks of *Empaglifozin Devatis 10 mg & 25 mg filmdragerade tabletter*, how these risks can be minimised, and how more information will be obtained about *Empaglifozin Devatis 10 mg & 25 mg filmdragerade tabletter* 's risks and uncertainties (missing information).

Empaglifozin Devatis 10 mg & 25 mg filmdragerade tabletter 's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how *Empaglifozin Devatis 10 mg & 25 mg filmdragerade tabletter* should be used.

Important new concerns or changes to the current ones will be included in updates of *Empaglifozin Devatis 10 mg & 25 mg filmdragerade tabletter* 's RMP.

I. The medicine and what it is used for

Empaglifozin Devatis 10 mg & 25 mg filmdragerade tabletter is authorised for:

Type 2 diabetes mellitus

Empaglifozin is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise

- as monotherapy when metformin is considered inappropriate due to intolerance
- in addition to other medicinal products for the treatment of diabetes

For study results with respect to combination of therapies, effects on glycaemic control, cardiovascular and renal events, and the populations studied, see sections 4.4, 4.5 and 5.1.

Heart failure

Empaglifozin is indicated in adults for the treatment of symptomatic chronic heart failure.

Chronic kidney disease

Empaglifozin is indicated in adults for the treatment of chronic kidney disease.

It contains empagliflozin as the active substance and it is given by oral administration.

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

Important risks of *Empaglifozin Devatis 10 mg & 25 mg filmdragerade tabletter*, together with measures to minimise such risks and the proposed studies for learning more about *Empaglifozin Devatis 10 mg & 25 mg filmdragerade tabletter* '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, including PSUR assessment 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 *Empaglifozin Devatis 10 mg & 25 mg filmdragerade tabletter* 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 *Empaglifozin Devatis 10 mg & 25 mg filmdragerade tabletter*. 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	• None
Important potential risks	• Urinary tract carcinogenicity • Pancreatitis
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 *Empaglifozin Devatis 10 mg & 25 mg filmdragerade tabletter*.

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

There are no studies required for *Empaglifozin Devatis 10 mg & 25 mg filmdragerade tabletter*.