ELPEN

Part VI: Summary of the risk management plan

Summary of risk management plan for DOFLIGA PLUS 5 mg+850 mg filmdragerade tabletter, DOFLIGA PLUS 5 mg+1000 mg filmdragerade tabletter, Dapagliflozin/Metformin ELPEN 5 mg+850 mg filmdragerade tabletter, Dapagliflozin/Metformin ELPEN 5 mg+1000 mg filmdragerade tabletter (Dapagliflozin/Metformin)

This is a summary of the risk management plan (RMP) for DOFLIGA PLUS, Dapagliflozin/Metformin ELPEN. The RMP details important risks of DOFLIGA PLUS, Dapagliflozin/Metformin ELPEN, how these risks can be minimised, and how more information will be obtained about DOFLIGA PLUS, Dapagliflozin/Metformin ELPEN's risks and uncertainties (missing information).

DOFLIGA PLUS, Dapagliflozin/Metformin ELPEN's summary of product characteristics (SmPC) and their package leaflet give essential information to healthcare professionals and patients on how DOFLIGA PLUS, Dapagliflozin/Metformin ELPEN should be used.

Important new concerns or changes to the current ones will be included in updates of DOFLIGA PLUS, Dapagliflozin/Metformin ELPEN's RMP.

I. The medicine and what it is used for

DOFLIGA PLUS, Dapagliflozin/Metformin ELPEN are authorised in adults for the treatment of type 2 diabetes mellitus as an adjunct to diet and exercise:

- in patients insufficiently controlled on their maximally tolerated dose of metformin alone
- in combination with other medicinal products for the treatment of diabetes in patients insufficiently controlled with metformin and these medicinal products
- in patients already being treated with the combination of dapagliflozin and metformin as separate tablets.

They contain dapagliflozin and metformin as the active substances and they are given orally.

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

Important risks of DOFLIGA PLUS, Dapagliflozin/Metformin ELPEN, together with measures to minimise such risks and the proposed studies for learning more about DOFLIGA PLUS, Dapagliflozin/Metformin ELPEN'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 DOFLIGA PLUS, Dapagliflozin/Metformin ELPEN are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal products 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 DOFLIGA PLUS, Dapagliflozin/Metformin ELPEN. Potential risks are concerns for which an association with the use of these medicines 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 products that is currently missing and needs to be collected (e.g. on the long-term use of the medicines).

List of important risks and missing information	
Important identified risks	• Lactic acidosis (metformin) • Diabetic ketoacidosis including events with atypical presentation (dapagliflozin)
Important potential risks	None
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 DOFLIGA PLUS, Dapagliflozin/Metformin ELPEN.

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

There are no studies required for DOFLIGA PLUS, Dapagliflozin/Metformin ELPEN.