Summary of risk management plan for Dibaglep (sitagliptin/dapagliflozin)

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

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

Important new concerns or changes to the current ones will be included in updates of Dibaglep's RMP.

I. The medicine and what it is used for

Type 2 diabetes mellitus

Dibaglep, fixed dose combination of sitagliptin and dapagliflozin 25 mg/10 mg film-coated tablets, is indicated as an adjunct to diet and exercise in adult patients aged 18 years and older with type 2 diabetes mellitus:

- when already being treated with the free combination of sitagliptin and dapagliflozin given concurrently, at the same dose level as in the fixed dose combination, but as separate products.

Dibaglep, fixed dose combination of sitagliptin and dapagliflozin 100 mg/10 mg film-coated tablets, is indicated as an adjunct to diet and exercise in adult patients aged 18 years and older with type 2 diabetes mellitus:

- to improve glycaemic control when metformin and sitagliptin do not provide adequate glycaemic control,
- when already being treated with the free combination of sitagliptin and dapagliflozin given concurrently, at the same dose level as in the fixed dose combination, but as separate products.

It contains sitagliptin/dapagliflozin as the active substances, and it is given by oral route.

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

Important risks of Dibaglep, together with measures to minimise such risks and the proposed studies for learning more about Dibaglep'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.

If important information that may affect the safe use of Dibaglep is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Dibaglep are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. 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 Dibaglep. 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).

Summary of safety concerns	
Important identified risks	• Diabetic Ketoacidosis including events with atypical presentation
Important potential risks	• Bladder cancer • Breast cancer • Pancreatic cancer • Prostate cancer
Missing information	• Exposure during pregnancy and lactation

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal products.

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 Dibaglep.

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

There are no studies required for Dibaglep.