PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Palbociclib film coated tablets 75 mg, 100 mg and 125 mg

This is a summary of the risk management plan (RMP) for Palbociclib film coated tablets 75 mg, 100 mg and 125 mg. The RMP details important risks of Palbociclib film coated tablets 75 mg, 100 mg and 125 mg, how these risks can be minimised and how more information will be obtained about Palbociclib film coated tablets 75 mg, 100 mg and 125 mg risks and uncertainties (missing information).

Palbociclib film coated tablets 75 mg, 100 mg and 125 mg, summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Palbociclib film coated tablets 75 mg, 100 mg and 125 mg should be used.

Important new concerns or changes to the current ones will be included in updates of Palbociclib film coated tablets 75 mg, 100 mg and 125 mg RMP.

I. The medicine and what it is used for

Palbociclib is authorised for treatment of HR-positive, HER2 negative locally advanced or metastatic breast cancer.

It contains Palbociclib as the active substance and it is given by oral route of administration. (See SmPC for full indication)

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

Palbociclib film coated tablets 75 mg, 100 mg and 125 mg together with measures to minimise such risks and the proposed studies for learning more about Palbociclib film coated tablets 75 mg, 100 mg and 125 mg, 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 the case of Palbociclib, these measures are supplemented with additional risk minimisation measures mentioned under relevant important risks, below.

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.

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

II.A List of important risks and missing information

Palbociclib film coated tablets 75 mg, 100 mg and 125 mg 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 Palbociclib film coated tablets 75 mg, 100 mg and 125 mg. 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	• Reproductive and Developmental Toxicity
Missing Information	• None

II.B Summary of important risks

Important Identified Risks	
Important Identified Risks:- None	
Important Potential Risks: Reproductive and Developmental Toxicity	
Risk minimisation measures	Routine risk minimisation measures SmPC Sections 4.6, 5.3 Additional risk minimisation measures None
Missing Information	• None

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 for Palbociclib film coated tablets 75 mg, 100 mg and 125 mg.

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

There are no studies required for Palbociclib film coated tablets 75 mg, 100 mg and 125 mg.