PUBLIC SUMMARY OF THE RISK MANAGEMENT PLAN

IBRANCE (Palbociclib)

Marketing Authorization Number 66138

Hard capsules, 75 mg; 100 mg; 125 mg

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LIST OF ABBREVIATIONS

EMA	European Medicines Agency
EPAR	European Public Assessment Report
EU	European Union
HR	Hormone receptor
HER2	Human epidermal growth factor receptor 2
PL	Package leaflet
PSUR	Periodic Safety Update Report
RMP	Risk Management Plan
SmPC	Summary of Product Characteristics (Europe)

OVERVIEW

The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks as well as to prevent or minimise them. The RMP summary for Ibrance is a concise document and does not claim to be exhaustive.

As the RMP is an international document, the summary might differ from the "Arzneimittelinformation / Information sur le médicament" approved and published in Switzerland, e.g., by mentioning risks occurring in populations or indications not included in the Swiss marketing authorization.

Please note that the reference document which is valid and relevant for the effective and safe use of Ibrance in Switzerland is the "Arzneimittelinformation / Information sur le médicament" (see www.swissmedic.ch) approved and authorised by Swissmedic. Pfizer is fully responsible for the accuracy and correctness of the content of the published RMP summary of Ibrance.

SUMMARY OF RISK MANAGEMENT PLAN FOR IBRANCE (PALBOCICLIB)

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

Ibrance's Summary of Product Characteristics (SmPC) and its Package Leaflet (PL) give essential information to healthcare professionals and patients on how Ibrance should be used.

This summary of the RMP for Ibrance should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

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

I. The Medicine and What It Is Used For

Ibrance 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.

Further information about the evaluation of Ibrance's benefits can be found in Ibrance's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage.

II. Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

Important risks of Ibrance, together with measures to minimise such risks and the proposed studies for learning more about Ibrance'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 PL 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 public with prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse events 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 Ibrance is not yet available, it is listed under 'missing information' below.

II.A. List of Important Risks and Missing Information

Important risks of Ibrance 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 Ibrance. 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. 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

Table 2. Summary of Important Risk or Missing information

Important Identified Risk: None	
Important Potential Risk: Reproductive and Developmental Toxicity	
Evidence for linking the risk to the medicine	Palbociclib clinical and non-clinical studies.
Risk factors and risk groups	No risk groups have been identified.
Risk minimisation measures	Routine risk minimisation measures: SmPC Sections 4.6, 5.3 PL Section: Pregnancy and breast-feeding and fertility 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 that are conditions of the marketing authorisation.

II.C.2. Other Studies in Post-Authorisation Development Plan

There are no studies required for palbociclib.