# PUBLIC SUMMARY OF THE RISK MANAGEMENT PLAN

## VIZIMPRO® (Dacomitinib)

Marketing Authorization Number 66774

Film-coated tablets, 15 mg, 30 mg, 45 mg

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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 to further investigate and follow the risks as well as to prevent or minimise them. The RMP summary for Vizimpro 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 Vizimpro 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 this published RMP summary of Vizimpro.

# SUMMARY OF THE RISK MANAGEMENT PLAN

## Summary of Risk Management Plan for Vizimpro

This is a summary of the Risk Management Plan (RMP) for Vizimpro. The RMP details the important risks of Vizimpro, how these risks can be minimised, and how more information will be obtained about the risks and uncertainties (missing information) of dacomitinib.

Vizimpro's Summary of Product Characteristics (SmPC) and its package leaflet provide essential information to Healthcare Professionals (HCPs) and patients on how dacomitinib should be used.

This summary of the RMP for Vizimpro 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).

New safety concerns or changes to the current ones will be included in updates of Vizimpro's RMP.

## I. The Medicine and What it is Used for

Vizimpro is a Tyrosine Kinase Inhibitor (TKIs). TKIs stop tyrosine kinases from working. Tyrosine kinases are enzymes that are responsible for activating many proteins in the body's cells causing cancer cells to grow and multiply.

Vizimpro is authorized for first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with EGFR-activating mutations (see SmPC for the full indication). Dacomitinib is the active substance to be taken orally. The recommended starting dose of dacomitinib is 45 mg taken once daily.

Further information about the evaluation of Vizimpro's benefits can be found in dacomitinib'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 Minimize or Further Characterize the Risks

Important risks of Vizimpro, together with measures to minimise such risks are outlined below.

Measures to minimise the risks identified for medicinal products are:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and Health Care Professionals (HCPs)
- 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 with prescription to help 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 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 dacomitinib is not yet available, it is listed under 'missing information' below.

## II.A. List of Important Risks and Missing Information

Important risks of Vizimpro 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 Vizimpro. 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** | Interstitial lung disease<br>Diarrhoea |
| **Important Potential Risks** | Hepatotoxicity<br>Reproductive and developmental toxicity |
| **Missing Information** | Patients with severe renal impairment |

## II.B. Summary of Important Risks and Missing Information

| **Summary of Important Risks and Missing Information** | |
|---|---|
| **Important Identified Risk: Interstitial Lung Disease (ILD)** | |
| Evidence for linking the risk to the medicine: | Dacomitinib non-clinical and clinical studies. |
| Risk factors and risk groups: | There are currently no known risk groups or risk factors for the development of ILD-like events in patients receiving dacomitinib. |
| Risk minimisation measures: | Routine risk minimisation measures:<br>SmPC sections 4.2, 4.4, 4.8<br><br>Additional risk minimisation measures:<br>None |
| **Important Identified Risk: Diarrhoea** | |

| Summary of Important Risks and Missing Information | |
|---|---|
| Evidence for linking the risk to the medicine: | Dacomitinib non-clinical and clinical studies. |
| Risk factors and risk groups: | Factors that could potentially be associated with an increased risk of diarrhoea include antibiotic use, side effects of other medications, intestinal abnormalities, food intolerance, and/or general wasting syndromes associated with cancer. |
| Risk minimisation measures: | Routine risk minimisation measures:<br>SmPC sections 4.2, 4.4, 4.8<br><br>Additional risk minimisation measures:<br>None |
| **Important Potential Risk: Hepatotoxicity** | |
| Evidence for linking the risk to the medicine: | Dacomitinib non-clinical and clinical studies. |
| Risk factors and risk groups: | Risk factors for drug-induced hepatotoxicity encompass a number of drug categories such as antimicrobials, drugs acting on the central nervous system, cardiovascular, rheumatologic, antineoplastic, and endocrine. Although no specific risk groups or risk factors have been identified with dacomitinib treatment, patients with prior history of hepatic disease or hepatitis before treatment may be at increased risk. |
| Risk minimisation measures: | Routine risk minimisation measures:<br>SmPC sections 4.2, 4.4, 4.8 (transaminases increased)<br><br>Additional risk minimisation measures:<br>None |
| **Important Potential Risk: Reproductive and Developmental Toxicity** | |
| Evidence for linking the risk to the medicine: | Dacomitinib non-clinical studies, other EGFR TKI non-clinical studies and literature. |
| Risk factors and risk groups: | Risk factors and risk groups include women of childbearing potential, pregnant women, and lactating women. |
| Risk minimisation measures: | Routine risk minimisation measures:<br>SmPC sections 4.6, 5.3<br><br>Additional risk minimisation measures:<br>None |
| **Missing Information: Patients with Severe Renal Impairment** | |
| Risk minimisation measures: | Routine risk minimisation measures:<br>SmPC sections 4.2, 5.2<br><br>Additional risk minimisation measures:<br>None |

SmPC = Summary of Product Characteristics

## II.C. Post-Authorisation Development Plan

Not applicable.

## II.C.1. Studies Which are Conditions of the Marketing Authorisation

There are no studies which are conditions of the marketing authorisation or a specific obligation of the dacomitinib program.

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

There are no studies required for dacomitinib