



Verzenios[®]

abemaciclib

film-coated tablets

Summary of Risk Management Plan (RMP)

Summary of the risk management plan (RMP) for Verzenios (abemaciclib)

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 minimize them.

The RMP summary of Verzenios 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 authorization. Please note that the reference document which is valid and relevant for the effective and safe use of Verzenios in Switzerland is the „Arzneimittelinformation/ Information sur le médicament“(see www.swissmedicinfo.ch) approved and authorized by Swissmedic.

Eli Lilly is fully responsible for the accuracy and correctness of the content of this published summary RMP of Verzenios.

I. The Medicine and What It Is Used for

VERZENIOS is authorised for locally advanced and metastatic breast cancer. It contains abemaciclib as the active substance and it is given orally as immediate release film-coated tablets: 50, 100, 150 and 200 mg.

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

Important risks of VERZENIOS, together with measures to minimise such risks and the proposed studies for learning more about VERZENIOS'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 product information addressed to patients and healthcare professionals.
- 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.

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

II.A. List of Important Risks and Missing Information

Important risks of VERZENIOS 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 VERZENIOS. 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	Exposure and Safety in Patients with Severe Renal Impairment

II.B. Summary of Important Risks

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

Important Potential Risk: Reproductive and Developmental Toxicity	
Evidence for linking the risk to the medicine	Abemaciclib works by interfering with a certain step in cell division. Because foetal development requires cell division, it is likely that abemaciclib inhibits foetal development. In rats, lower foetal weight and other effects were observed, which is consistent with the classification of this risk as a potential risk. No human data are available.
Risk factors and risk groups	Chemotherapy exposure during pregnancy carries a higher risk of spontaneous abortion and major birth defects. Older patients (over age 40 years) are more likely to develop early menopause after chemotherapy. Additional risk factors include smoking, drinking alcohol, diabetes and obesity.
Risk minimisation measures	Abemaciclib is not recommended during pregnancy and in women of child-bearing potential who are not using birth control. Women of child-bearing potential should use a highly effective birth control method during treatment and for 3 weeks following treatment.

Missing Information: Exposure and Safety in Patients with Severe Renal Impairment	
Risk minimisation measures	Use of abemaciclib in patients with severe renal impairment is not contraindicated. Abemaciclib should be administered with caution in patients with severe renal impairment. Complete blood counts should be monitored before starting abemaciclib therapy and every 2 weeks for the first 2 months of therapy.

VI.1.1. II.C. Post-authorisation development plan

VI.1.1.1. II.C.1. Studies that are conditions of the marketing authorisation

There are no studies that are conditions of the marketing authorisation or specific obligation of VERZENIOS.

VI.1.1.2. II.C.2. Other studies in the post-authorisation development plan

Not applicable

