Summary of the Risk Management Plan for Verquvo®

Active substance: Vericiguat

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Verquvo®
(Vericiguat)
Risk Management Plan

Summary of activities in the risk management plan

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 of Verquvo® 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 Verquvo® in Switzerland is the "Arzneimittelinformation/ Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic. Bayer (Schweiz) AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of Verquvo®.

Summary of Risk Management Plan for Verquvo®

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

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

This summary of the RMP for Verquvo® 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 Verquvo®'s RMP.

1. The Medicine and what it is used for

Verquvo® is indicated for the treatment of symptomatic chronic heart failure in adult patients with reduced ejection fraction who are stabilised after a recent decompensation event requiring IV therapy. It is administered in conjunction with other heart failure therapies (see SmPC for the full indication). It contains vericiguat as the active substance and it is given by oral administration.

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

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2. Risks Associated with the Medicine and Activities to Minimise or further Characterise the Risks

Important risks of Verquvo®, together with measures to minimise such risks and the proposed studies for learning more about Verquvo®'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, 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 Verquvo® is not yet available, it is listed under 'missing information' below.

2.1 List of Important Risks and Missing Information

Important risks of Verquvo® 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 Verquvo®. 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	None
Important potential risks	None
Missing information	Use in patients with severe renal impairment (eGFR <15 mL/min/1.73 m^2) Use in patients with severe hepatic impairment

2.2 Summary of Important Risks List of Important Risks and Missing Information

Missing information: Use in patients with severe renal impairment (eGFR <15 mL/min/1.73 m_2)	
Risk minimisation measures	
Routine risk communication:	• SmPC sections 4.2 and 5.2.
Routine risk communication recommending specific clinical measure to address the risk:	• Treatment with vericiguat is not recommended in patients with eGFR <15 mL/min/1.73 m_2 at treatment initiation or on dialysis (SmPC Section 4.4)
Other routine risk minimisation measures beyond the Product Information:	• Prescription-only medicine
Additional risk minimisation measures:	None

Missing information: Use in patients with severe hepatic impairment	
Risk minimisation measures	
Routine risk communication:	• SmPC sections 4.2 and 5.2
Routine risk communication recommending specific clinical measure to address the risk:	• Treatment with vericiguat is not recommended in patients with severe hepatic impairment (SmPC Section 4.4)
Other routine risk minimisation measures beyond the Product Information:	• Prescription-only medicine
Additional risk minimisation measures:	None

3. Post-authorisation Development Plan

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