

# Summary of the Risk Management Plan for Kerendia<sup>®</sup>

Active substance: Finerenone

Version number: version 3.0

Document date: 27-January-2023

Based on the EU-RMP v2.2 dated 14-December-2022 for Kerendia<sup>®</sup>



**Kerendia®**  
(Finerenone)  
Risk Management Plan

**Summary of activities in the risk management plan**

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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 in order to further investigate and follow the risks as well as to prevent or minimise them.

The RMP summary of Kerendia® 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 Kerendia® in Switzerland is the “Arzneimittelinformation/ Information sur le médicament” (see [www.swissmedic.ch](http://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 Kerendia®.

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**1. Summary of Risk Management Plan for Kerendia<sup>®</sup>**

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

Kerendia<sup>®</sup>'s Summary of Product Characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Kerendia<sup>®</sup> should be used.

This summary of the RMP for Kerendia<sup>®</sup> 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 Kerendia<sup>®</sup>'s RMP.

**2. The Medicine and What It is Used for**

Kerendia<sup>®</sup> is authorised for “the treatment of chronic kidney disease (with albuminuria) associated with type 2 diabetes in adults. For study results with respect to renal and cardiovascular events, see section 5.1”. It contains finerenone as the active substance and it is given by oral administration.

Further information about the evaluation of Kerendia<sup>®</sup>'s benefits can be found in Kerendia<sup>®</sup>'s European Public Assessment Report (EPAR), including in its plain-language summary, available on the EMA website:

<https://www.ema.europa.eu/en/medicines/human/EPAR/kerendia>

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

Important risks of Kerendia<sup>®</sup>, together with measures to minimise such 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.

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In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR 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 Kerendia® is not yet available, it is listed under ‘missing information’ below.

### **3.1 List of Important Risks and Missing Information**

Important risks of Kerendia® 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 Kerendia®. 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).

#### **3.1.1 Summary table of safety concerns**

<b>Summary of safety concerns</b>	
Important identified risks	Hyperkalemia
Important potential risks	Embryo-foetal toxicity
Missing information	Use in pregnancy and lactation

#### **3.2 Summary of important risks**

<b>Important identified risk - Hyperkalemia</b>	
Evidence for linking the risk to the medicine	The evidence is based on two pivotal Phase III studies FIDELIO- DKD (#16244) and FIGARO-DKD (#17530) conducted in patients with chronic kidney disease and type 2 diabetes.
Risk factors and risk groups	Hyperkalemia is a known complication of reduced renal function in patients with CKD. Besides CKD, the most common risk factors for hyperkalemia include cardiovascular disease, diabetes mellitus and concomitant use of drugs which raise the potassium concentration (e.g., ACEIs, ARBs, potassium-sparing diuretics, and beta- blockers).  Based on the analyses of two pivotal Phase III studies FIDELIO- DKD and FIGARO-DKD, risk factors for hyperkalemia include low eGFR, higher baseline serum

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<b>Important identified risk - Hyperkalemia</b>	
	potassium and previous episodes of hyperkalemia. Concomitant use of finerenone with CYP3A4 inhibitors may be associated with a higher risk of developing hyperkalemia due to an increase in finerenone exposure.
Risk minimisation measures	<p><b>Routine risk minimisation measures</b></p> <ul style="list-style-type: none"> <li>• SmPC sections: 4.2, 4.4, 4.5 and 4.8</li> <li>• Kerendia® is a prescription-only medicine</li> </ul> <p><b>Additional risk minimisation measures</b></p> <ul style="list-style-type: none"> <li>• None</li> </ul>

<b>Important potential risk - Embryo-foetal toxicity</b>	
Evidence for linking the risk to the medicine	The evidence is based on non-clinical data in the developmental toxicity studies in the rat as well as literature data of other MRAs. There are no clinical data on the use of finerenone in pregnant women.
Risk factors and risk groups	Women of childbearing potential.
Risk minimisation measures	<p><b>Routine risk minimisation measures</b></p> <ul style="list-style-type: none"> <li>• SmPC section 4.4 Special warnings and precautions for use</li> <li>• SmPC section 4.6 Fertility, pregnancy and lactation</li> <li>• SmPC section 5.3 Preclinical safety data</li> <li>• Kerendia® is a prescription-only medicine</li> </ul> <p><b>Additional risk minimisation measures</b></p> <ul style="list-style-type: none"> <li>• None</li> </ul>

<b>Missing information – Use in pregnancy and lactation</b>	
Risk minimisation measures	<p><b>Routine risk minimisation measures</b></p> <ul style="list-style-type: none"> <li>• SmPC section 4.4 Special warnings and precautions for use</li> <li>• SmPC section 4.6 Fertility, pregnancy and lactation</li> </ul>

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<b>Missing information – Use in pregnancy and lactation</b>	
	<ul style="list-style-type: none"><li>• SmPC section 5.3 Preclinical safety data</li><li>• Kerendia® is a prescription-only medicine</li></ul> <p><b>Additional risk minimisation measures</b></p> <ul style="list-style-type: none"><li>• None</li></ul>

**4. Post-authorisation Development Plan**

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