Summary of the Risk Management Plan for NEXAVAR®

Active substance: Sorafenib

Version number: version 1.0

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Based on the EU-RMP v13.1 dated 07-Jan-2025 for NEXAVAR®

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 NEXAVAR® 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 NEXAVAR® 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 NEXAVAR®.

Summary of Risk Management Plan

This is a summary of the RMP for Nexavar. There are currently no important risks of Nexavar according to the definitions given in the GVP, Module V, Revision 2.

Nexavar's SmPC and its package leaflet give essential information to healthcare professionals and patients on how Nexavar should be used.

This summary of the RMP for Nexavar 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 Nexavar's RMP.

I. The medicine and what it is used for

Nexavar is authorised for advanced RCC, HCC, and locally advanced or metastatic DTC refractory to RAI (see SmPC for the full indication). It contains sorafenib (as tosylate) as the active substance and it is given orally.

Further information about the evaluation of Nexavar's benefits can be found in Nexavar's EPAR, including in its plain-language summary, available on the European Medicines Agency (EMA) website, under the medicine's webpage:
https://www.ema.europa.eu/medicines/human/EPAR/nexavar

II. Risks associated with the medicine and activities to minimise or further characterise the risks

As none of the identified and potential risks of Nexavar are judged as important, there are no additional pharmacovigilance activities and risk minimization measures related to the product beyond those described above in this Section of the document.

II.A List of important risks and missing information

None of the identified and potential risks of Nexavar are considered important according to the definitions given in the GVP, Module V, Revision 2.

Table Part VI-1: Summary of safety concerns

Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

There are no important identified/potential risks or missing information included in the list of safety concerns.

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Nexavar.

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

Not Applicable.