Radelumin 200 – 4500 MBq/mL, solution for injection

Summary of Risk Management Plan

Active substance: [^{18}F]PSMA-1007

Document status: Version 1.0

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Marketing Authorization Holder: Posimed Radiopharm AG, 3011 Bern

The risk management plan (RMP) is a comprehensive document submitted as a 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 follows the risks as well as prevent or minimize them.

The RMP summary of Radelumin 200 – 4500 MBq/mL, solution for injection, 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" approved and published in Switzerland e.g. by mentioning risk occurring in populations not included in the swiss authorization.

Please note, that the reference document which is valid and relevant for the effective and safe use of Radelumin 200 – 4500 MBq/mL, solution for injection, is the "Arzneimittelinformation" approved and authorized by Swissmedic. Posimed Radiopharm AG is fully responsible for the accuracy and correctness of the content of the here published summary RMP of Radelumin 200 – 4500 MBq/mL solution for injection.

Summary of the risk management plan (RMP) for Radelumin 200 – 4500 MBq/ml, solution for injection

This is a summary of the RMP for Radelumin. This summary should be read in the context of all this information including the assessment report of the evaluation and its plain-language, 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 Radelumin RMP.

I. The medicine and what it is used for

Radelumin is a radioactive diagnostic agent indicated for imaging prostate-specific membrane antigen (PSMA)-positive lesions by positron emission tomography (PET) in adult patients with prostate cancer.

It contains [^{18}F]PSMA-1007 as the active substance and is injected intravenously.

Further information about the evaluation of Radelumin benefits can be found in Radelumin´s EPAR including in its plain language summary, available on the European Medicines agency website.

II. Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of Radelumin, together with measures to minimize such risks and to proposed studies for learning more about Radelumin risks, are outlined below.

Measures to minimize the risks identified to medical products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the medical product information addressed to healthcare professionals;
- Important advises on the medicine´s packaging;
- The authorized 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 minimize its risks.

In the case of Radelumin, these measures are supplemented with additional risk minimization measures mentioned under relevant important risks, below.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, including PSUR assessment so that immediate action can be taken as necessary. These measures constitute routine Pharmacovigilance activities.

II.A List of important risks and missing information

Important risks of Radelumin are risks that need special risk management activities to further investigate or minimize the risk, so that the medical product can be safety administered. 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 Radelumin. 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 medical product that is currently missing and needs to be collected.

List of important risks missing information	
Important identified risks	None
Important potential risks	PET imaging interpretation errors
Missing information	None

II.B Summary of important risks

Important potential risks **PET imaging errors**	
Evidence for linking the risk to the medicine	Problems may occur in the incorrect interpretation of findings of the PET-imaging. Especially wrong positive findings may occur in the skeleton, caused by non-metastatic diseases. False positive findings are also known to be originated by tumors other than prostate cancer also bearing PSMA receptors
Other factors	Problems may occur when the amount of radioactivity injected will be extremely exceeded. The problem will not arise from the pharmaceutical but from the amount of radioactivity.
Additional pharmacovigilance activities	Constant literature research

II.C Post-authorization development plan

II.C1 Studies which are conditions of the marketing authorization

There are no studies that are conditions of the marketing authorization or specific obligation of Radelumin.

II.C2 Other studies in post-authorization development plan

There are no studies planned at the moment.