Public Risk Management Plan (RMP) Summary

For

NETSPOT 40 micrograms kit for radiopharmaceutical preparation

Version 2.0 (07-Jan-2021)

Disclaimer

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 Gallium (68Ga) oxodotreotide "NETSPOT" 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 Gallium (68Ga) oxodotreotide "NETSPOT" in Switzerland is the "Arzneimittelinformation / Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic. "Advanced Accelerator Applications International SA" is fully responsible for the accuracy and correctness of the content of the published summary RMP of Gallium (68Ga) oxodotreotide "NETSPOT".

Part VI: Summary of the risk management plan

Summary of risk management plan for NETSPOT

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

NETSPOT's summary of product information/product monograph and its package leaflet give essential information to healthcare professionals and patients on how NETSPOT should be used.

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

Important new concerns or changes to the current ones will be included in updates of NETSPOT's RMP.

I. The medicine and what it is used for

NETSPOT is a Kit for the preparation of gallium Ga 68 dotatate **for injection,** authorised for use with special camera that uses radiation to look at the structure and functioning of parts of the body [positron emission tomography (PET)] for localization of somatostatin receptor positive neuroendocrine tumors (NETs).
It contains Gallium (68Ga) oxodotreotide as the active substance and it is given by IV route of administration.

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

Important potential risk of NETSPOT, together with measures to minimise such risks, are outlined below.

II.A List of important risks and missing information

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 NETSPOT. 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	None

List of important risks and missing information	
Missing information	Use in lactation, use in paediatric population, use in patient with renal (kidney) or hepatic (liver) impairment

II.B Summary of important risks

There are no important identified or potential risks for NETSPOT.

Missing information: Use in Use in lactation, Use in Paediatric population, Use in patients with renal or hepatic impairment	
Risk factors and risk groups	Breast feeding women, age under 18 year-old and patient with renal or hepatic impairment
Risk minimisation measures	Routine risk minimisation measures: - NETSPOT Product information/ product monograph. - Patient leaflet - Prescription and administration only by nuclear physician - Reports on administration to patients with renal or hepatic impairment.
Additional pharmacovigilance activities	Additional pharmacovigilance activities: None

II.C Post-authorisation development plan

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

Not applicable

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

There are no studies required for NETSPOT.