NOVARTIS

Regulatory Affairs

Drug generic name

Summary of the EU Safety Risk Management Plan

Active substance(s) (INN or common name):	*Gallium (^{68}Ga) oxodotreotide*
Product(s) concerned (brand name(s)):	*Netpsot*
Document status:	*Final*
Version number of the RMP Public Summary:	*3.0*
Date of final sign off of the RMP Public Summary	*30-Jan-2024*

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 “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 “Netspot” in Switzerland is the “Arzneimittelinformation/ Information sur le médicament” (see www.swissmedic.ch) approved and authorized by Swissmedic. Novartis Pharma Schweiz AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of “Netspot”.

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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,** authorized 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 minimize or further characterize the risks

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 the medicinal product. 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).

Table 1 List of important risks and missing information

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	None

II B: Summary of important risks

There are no important identified or potential risks or missing information for NETSPOT.

II C: Post-authorization development planII.C.1 Studies which are conditions of the marketing authorization

There are no studies which are conditions of the marketing authorization or specific obligation of NETSPOT..

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

There are no studies required for NETSPOT.