Regulatory Affairs

Locametz

Summary of the Local Safety Risk Management Plan

Active substance(s) (INN or common name):	*gallium (^{68}Ga) gozetotide*
Product(s) concerned (brand name(s)):	*Locametz®*
Document status:	*Final*
Version number of the RMP Public Summary: *(aligned with corresponding RMP version)*	*1.0*
Date of final sign off of the RMP Public Summary *(this is referring to this document)*	*21-April-2023*

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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 “Locametz” 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 “Locametz” in Switzerland is the “Arzneimittelinformation/ Information sur le médicament” (see www.swissmedic.ch) approved and authorized by Swissmedic. Advanced Accelerator Applications International is fully responsible for the accuracy and correctness of the content of the published summary RMP of “Locametz”.

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Summary of the risk management plan for Locametz (gallium (^{68}Ga) gozetotide)

This is a summary of the RMP for Locametz. The RMP details important risks of Locametz, how these risks can be minimized, and how more information will be obtained about Locametz's risks and uncertainties (missing information).

Locametz's summary of product characteristics (SmPC) and its package leaflet give essential information to health care professionals and patients on how Locametz should be used.

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

I. The medicine and what it is used for

Locametz after radiolabeling with gallium-68, is a radioactive diagnostic agent indicated for the identification of prostate-specific membrane antigen (PSMA) positive lesions by Positron Emission Tomography (PET) in adult patients with prostate cancer.

Locametz is a multidose kit for radiopharmaceutical preparation of gallium (68Ga) gozetotide solution for injection, containing one vial of white lyophilized powder (powder for solution for injection). Locametz is for radiolabeling with gallium-68 chloride solution.

Further information about the evaluation of Locametz’s benefits can be found in Locametz’s EPAR, including in its plain-language summary, available on the EMA website, under the medicine’s webpage.

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

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

Measures to minimize 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 minimize its risks.

Together, these measures constitute routine risk minimization measures.

II.A: List of important risks and missing information

Important risks of Locametz's are risks that need special risk management activities to further investigate or minimize the risk, so that the medicinal product can be safely 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 Locametz. 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	Hypersensitivity
Missing information	None

II B: Summary of important risks

Table 2 Important potential risk – Hypersensitivity

Evidence for linking the risk to the medicine	Theoretical risk, currently low strength of evidence. Case reports exist for other diagnostic agents
Risk factors and risk groups	Preexisting allergic conditions, however severe life-threatening reactions are often unpredictable
Risk minimization measures	**Routine risk minimization measures** Sec 4.3 of the SmPC. **Additional risk minimization measures** None

II C: Post-authorization development plan

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

None

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

There are no studies required for Locametz.