VI.2 Elements for a Public Summary

VI.2.1 Overview of Disease Epidemiology

Galli Ad has no clinical indications on its own. The eluate $^{68}GaCl_3$ is used to radiolabel specific carrier molecules that are used for diagnostic imaging with positron emission tomography (PET) of a lot of conditions. The conditions identified through literature review are:

- Prolonged exposure to cortisol (Cushing's syndrome)
- Brain tumor (Meningioma)
- Pancreas cancer (Neuroendocrine tumour)
- Prostate cancers
- Other cancers
- Assessment of pulmonary function

VI.2.2 Summary of Treatment Benefits

The major application domain of PET with ^{68}Ga radiolabelled molecule is in oncology. However, potential has been demonstrated for imaging of myocardial perfusion, pulmonary perfusion and ventilation as well as inflammation and infection. This imaging method has shown to provide more accurate and quantitative diagnosis, enabling, for example, individualized cancer therapy planning, resulting in the efficient and cost saving treatment.

^{68}Ga as various advantages compared to other radionuclides used as imaging agents. It is produced from a long shelf-life and cost-effective generator. The labelling synthesis is amenable to automation and kit type preparation. The half-life of ^{68}Ga permits production and application of resultant agents. It provides sufficient levels of radioactivity for high quality images, short scanning time (fast patient examination) while minimizing the radiation dose to the patient and personnel, and allows fast dischargement of the patient. It also allows repetitive examinations within the same day.

VI.2.3 Unknowns Relating to Treatment Benefits

The eluate gallium (^{68}Ga) chloride solution is used for in vitro radiolabelling of specific carrier molecules to be used for diagnostic imaging with PET. Treatment benefits could be more investigated with those molecules which are radiolabelled with the eluate ^{68}Ga chloride solution.

VI.2.4 Summary of Safety Concerns

Table 3: Important Identified Risks

Risk	What is known	Preventability
Not applicable	-	-

Table 4: Important Potential Risks

Risk	What is known (Including reason why it is considered a potential risk)
Accidental direct use in patients	The direct administration of the eluate consisting of 0.1 mol/L hydrochloric acid may cause local venous irritation, but would quickly be diluted in the blood. The seriousness is expected to be low, with a favourable outcome. Even though the product is for use in designated nuclear medicine facilities only, and should only be handled by specialists experienced with in vitro radiolabelling, a human error is possible. No case has been reported so far.
^{68}Ge breakthrough	The ^{68}Ge breakthrough for Galli Ad is not more than 0.001% throughout the shelf-life of the product when used in the conditions described in the SmPC. Studies have demonstrated that radioactivity resulting from ^{68}Ge breakthrough is extremely low in rats, with the highest ^{68}Ge radioactivity seen in the urine and liver ($\leq 2 \times 10^{-4}$% of the injected dose per gram, 5 min to 3 h after injection). The limit defined in the European Pharmacopoeia monograph could be increased at least 100 times without compromising patient safety. A device failure is unlikely to happen. but ^{68}Ge breakthrough could occur if the instructions provided in the SmPC to reduce the risk or to test the ^{68}Ge breakthrough are not followed by the by specialists experienced with in vitro radiolabelling. No case has been reported so far.
Carcinogenicity and hereditary effects	Carcinogenicity and hereditary effects are a class effect related to ionising radiation that cannot be totally excluded for exposure to ^{68}Ga. No case has been reported so far.
Occupational and inadvertent exposure to radiation	The administration of radiopharmaceuticals creates risks for other persons from external radiation or contaminations. Therefore, occupational and inadvertent exposure to radiation is considered as a potential risk of Galli Ad. No case has been reported so far.

Table 5: Missing Information

Risk	What is known
Not applicable	-

VI.2.5 Summary of Additional Risk Minimisation Measures by Safety Concern

All medicines have a Summary of Product Characteristics (SmPC) which provides physicians, pharmacists and other health care professionals with details on how to use the medicine, the risks and recommendations for minimising them. An abbreviated version of this in lay language is provided in the form of the Package Leaflet (PL). The measures in these documents are known as routine risk minimisation measures.

This risk-management system is part of the decentralized procedure for marketing authorisation of Galli Ad. Therefore, the Summary of Product Characteristics and the Package Leaflet for Galli Ad are not yet part of any EPAR.

This medicine has no additional risk minimisation measures.

VI.2.6 Planned Post-Authorisation Development Plan

This section is not applicable as no post-authorisation development plan is required.

VI.2.7 Summary of Changes to the Risk Management Plan over Time

This section is not applicable as this is the first version of the Risk Management Plan submitted for this medicinal product.