Part VI: Summary of the risk management plan

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

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

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

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

I. The medicine and what it is used for

isoPROtrace is authorised for diagnostic use only. IsoPROtrace, after radiolabelling with gallium (^{68}Ga) chloride solution, is indicated for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA)-positive lesions in men with prostate cancer:

- with suspected recurrence based on elevated serum prostate-specific antigen (PSA) level.
- with suspected metastasis who are candidates for initial definitive therapy.

It contains gallium (^{68}Ga) gozetotide as the active substance and it is given by intravenous route of administration.

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

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

Measures to minimise 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 minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, 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 isoPROtrace are risks that need special risk management activities to further investigate or minimise 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 isoPROtrace. 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	• PET imaging interpretation errors
Missing information	None

II.B Summary of important risks

Important potential risk - PET imaging interpretation errors	
Risk minimisation measures	<u>Routine risk minimisation measures:</u> SmPC section 4.2 and 4.4 PL section 3 <u>Legal status:</u> Prescription only medicines <u>Additional risk minimisation measures:</u> Educational materials for HCPs: An online or/and in-person (when online training is not accessible) image interpretation training containing the following information: • Biochemical basics • Patient administration and scanning protocol • Image reading and interpretation guidelines • PSMA PET in the context of other imaging modalities and histopathology • Interpretation of gallium (68Ga) gozetotide PET scans in different use scenarios and comprehensive case study reviewes (case studies with image interpretation provided by an expert) • Self-assessment test <u>Routine pharmacovigilance activities:</u> AE/ADRs relating to PET imaging interpretation errors will be evaluated in the PSURs. <u>Additional pharmacovigilance activities:</u> None

II.C Post-authorisation development plan

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

There are no studies which are conditions of the marketing authorisation or specific obligation of isoPROtrace.

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

There are no studies required for isoPROtrace.