VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

This section can be omitted for diagnostic products

VI.2.2 Summary of treatment benefits

Thyroid Scintigraphy

During the last almost 50 years, thyroid scintigraphy with ^{99m}Tc pertechnetate has proven its clinical usefulness and is a well-established procedure in clinical routine. Evidence about the frequent use of thyroid scintigraphy with ^{99m}Tc pertechnetate is available in numerous publications found in the peer-reviewed literature. The value of this diagnostic method was proven in hyperthyroidism and the evaluation of thyroid nodules and in other indications like congenital hypothyroidism and the identification of ectopic thyroid tissue (Smith JR et al, 2004; Lobo G et al, 2003). The use of (quantitative) thyroid scintigraphy is regarded as an established method for assessment of thyroid nodules and for identification of hyperfunctioning nodules in patients with suppressed TSH. Thyroid ^{99m}Tc scintigraphy is recommended in guidelines published by endocrine and nuclear medicine societies (Gharib H et al, 2008).

Salivary Gland Scintigraphy

Sjögren's syndrome (also known as "Mikulicz disease" and "sicca syndrome") is a systemic autoimmune disease which leads to destruction of exocrine glands that produce tears and saliva. The functional consequences of Sjögren's syndrome on the salivary glands can be quantitatively assessed with salivary gland scintigraphy ("sialoscintigraphy"). Sodium pertechnetate (^{99m}Tc) salivary gland scintigraphy provides quantitative information about saliva production in patients with Sjögren's syndrome to assist in the diagnosis of the

disease and in the follow-up of patients. For the diagnosis of Sjögren's syndrome, salivary gland scintigraphy showed higher sensitivity than MR sialography. On the other hand, MR sialography showed higher specificity and positive predictive value (PPV) than salivary gland scintigraphy. Overall diagnostic accuracy was 83% for MR sialography and 72% for salivary gland scintigraphy (Tonami H et al, 2001).

Salivary gland scintigraphy is a useful tool to quantitatively assess and follow-up patients after radiation exposure of the head and neck region, in particular after iodine-131 therapy since the results indicate that salivary gland scintigraphy enables early diagnosis of parenchymal damage after radiaton exposure (Bohuslavizki KH, 1996). In addition, salivary gland scintigraphy is assumed to provide an effective means to identify patients with already compromised salivary gland function prior to radioiodine therapy; in these patients a reduction of radioiodine dose or additional protective measures should be considered.

Detection of concrements in salivary ducts is usualy achieved by morphological imaging methods like ultrasound, MRI or CT. Salivary gland scintigraphy, in addition, provides information about the relevance of the obstruction, may add important information for planning of the surgical procedure, and permits a quantitative follow-up after removal of the obstruction(Yoshimura Y et al, 1989).

Localization of Ectopic Gastric Mucosa (Meckel's diverticulum)

Sodium pertechnetate (^{99m}Tc) scintigraphy for detection of Meckel's diverticulum delivers relevant information for treatment selection and patient management. The cumulative experience from prospective as well as retrospective studies confirms high specificity and diagnostic accuracy of sodium pertechnetate (^{99m}Tc) scintigraphy (>95% and 90-98%, respectively) [Brown RL et al, 1999; Swaniker F et al, 1999, Conolly LP et al, 1998; Kong MS et al, 1993; Poulsen KA et al, 2000) in children and adults. The lower sensitivity reported by most groups (values between 58% and 85%) is regarded as acceptable since the Meckel scan is the only test which can specifically detect Meckel's diverticulum and explorative laparoscopy (the alternative diagnostic procedure) is highly invasive.

SPECT techniques were developed recently, with the potential to increase the sensitivity of the Meckel scan. Repetition of the Meckel scan in case of a negative result, eventually by using pre-medication, is also assumed to increase the value of this test and is recommended by some authors (Kong MS et al, 1994).

Lacrimal Duct Scintigraphy

According to the current state of scientific knowledge, based on original papers, reviews and textbooks for nuclear medicine, dacryoscintigraphy is an established and important method for assessing the patency of the lacrimal ducts (Peter NM et al, 2009; Ziccardi VB et al, 2010).

VI.2.3 Unknowns relating to treatment benefits

Not identified.

VI.2.4 Summary of safety concerns

Important identified and potential risks

Risk	What is known	Preventability
Radiotoxicity to thyroid	This risk results from high affinity to thyroid tissue when the sodium pertechnetate (^{99m}Tc) solution circulated in the blood may be trapped by thyroid	Yes, by giving to the patient a thyroid blocking agent prior to examination. The thyroid blocking agent is given to avoid false positives or to minimise irradiation by reduction of pertechnetate accumulation in the thyroid and salivary glands Moreover for each patient, the radiation exposure must be justifiable by the likely benefit. The activity administered should in every case be as low as reasonably achievable to obtain the required diagnostic information.
Cancer, chromosomal mutations	This risk results from ionising radiation that is linked with cancer induction and a potential for development of hereditary defects.	Yes, by appropriate selection of administered activity for the individual patient. As the effective dose is 5.2 mSv when the maximal recommended activity of 400 MBq is administered these adverse reactions are expected to occur with a low probability.
Hypersensivity including anaphylactic reactions	This risk results from hypersensitivity to the active substance or to any of the	Yes, by collecting via interview with the patient, all important information if he/she is taking,

Risk	What is known	Preventability
	excipients: sodium chloride or water for injection.	have recently taken or might take any other medicines and if he/she suffers from allergies. If hypersensitivity or anaphylactic reactions occur, the administration of the medicinal product must be discontinued immediately and intravenous treatment initiated, if necessary. To enable immediate action in emergencies, the necessary medicinal products and equipment such as endotracheal tube and ventilator must be immediately available.
Occupational exposure	The administration of radioactive medicinal products creates risks for other persons from external radiation or contamination from spills of urine, vomiting, etc.	Yes, avoiding unnecessary exposure by reading complete information of the radiopharmaceutical product before starting the preparation procedure and administration to the patient by personnel Proper precautions for handling radioactive materials must be employed.

VI.2.5 Summary of risk minimisation measures by safety concern

The medicinal product Poltechnet, radionuclide generator, has 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 medicine has only routine measures and no additional risk minimisation measures.

VI.2.6 Planned post authorisation development plan

Not applicable, as no requirement of post authorisation development studies has been identified for the medicinal product Poltechnet, radionuclide generator.

VI.2.7 Summary of changes to the Risk Management Plan over time

Not applicable, as this is the first Risk Management Plan for the medicinal product Poltechnet, radionuclide generator and no changes have been made to the RMP over time.