**ANNEX I**

**SUMMARY OF PRODUCT CHARACTERISTICS**

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 for how to report adverse reactions.

## 1. NAME OF THE MEDICINAL PRODUCT

Locametz 25 micrograms kit for radiopharmaceutical preparation

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

The vial contains 25 micrograms of gozetotide.

The radionuclide is not part of the kit.

Excipient with known effect

The vial contains 28.97 mg of sodium.

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Kit for radiopharmaceutical preparation
One vial of white lyophilised powder (powder for solution for injection).

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

This medicinal product is for diagnostic use only.

Locametz, after radiolabelling with gallium-68, is indicated for the detection of prostate-specific membrane antigen (PSMA)-positive lesions with positron emission tomography (PET) in adults with prostate cancer (PCa) in the following clinical settings:

- Primary staging of patients with high-risk PCa prior to primary curative therapy,
- Suspected PCa recurrence in patients with increasing levels of serum prostate-specific antigen (PSA) after primary curative therapy,
- Identification of patients with PSMA-positive progressive metastatic castration-resistant prostate cancer (mCRPC) for whom PSMA-targeted therapy is indicated (see section 4.4).

### 4.2 Posology and method of administration

This medicinal product should only be administered by trained healthcare professionals with technical expertise in using and handling nuclear medicine imaging agents and only in a designated nuclear medicine facility.

Posology

The recommended dose of gallium ($^{68}$Ga) gozetotide is 1.8-2.2 MBq/kg of body weight, with a minimum dose of 111 MBq up to a maximum dose of 259 MBq.

*Special populations*
*Elderly*
No dose adjustment is required in patients aged 65 years and above.

*Renal impairment*
There are no data with gallium ($^{68}$Ga) gozetotide in patients with moderate to severe/end-stage renal impairment. No dose adjustment is considered necessary in patients with renal impairment (see section 5.2).

*Hepatic impairment*
No dose adjustment is required in patients with hepatic impairment (see section 5.2).

*Paediatric population*
There is no relevant use of Locametz in the paediatric population for the identification of PSMA-positive lesions in prostate cancer.

Method of administration

This medicinal product is for intravenous and multidose use. It should be reconstituted and radiolabelled before administration to the patient.

After reconstitution and radiolabelling, gallium ($^{68}$Ga) gozetotide solution should be administered by slow intravenous injection. Local extravasation resulting in inadvertent radiation exposure to the patient and imaging artefacts should be avoided. The injection should be followed by an intravenous flush of sterile sodium chloride 9 mg/ml (0.9%) solution for injection to ensure full delivery of the dose.

The total radioactivity in the syringe should be verified with a dose calibrator immediately before and after administration to the patient. The dose calibrator must be calibrated and comply with international standards. Instructions regarding the dilution of the gallium ($^{68}$Ga) gozetotide solution should be followed (see section 12).

For patient preparation, see section 4.4.

For instructions on reconstitution and radiolabelling of the medicinal product before administration, see section 12.

*Image acquisition*
Gallium ($^{68}$Ga) gozetotide PET image acquisition should be performed by scanning the whole body starting at mid-thigh and proceeding to skull base. PET images should be acquired 50 to 100 minutes after the intravenous administration of gallium ($^{68}$Ga) gozetotide solution.

Image acquisition start time and duration should be adapted to the equipment used, the patient and the tumour characteristics, in order to obtain the best image quality possible.

Use of computer tomography (CT) or magnetic resonance imaging (MRI) for attenuation correction is recommended.

## 4.3 Contraindications

Hypersensitivity to the active substance, to any of the excipients listed in section 6.1 or to any of the components of the labelled radiopharmaceutical.

## 4.4 Special warnings and precautions for use

Individual benefit/risk justification

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.

To date no outcome data exist to inform subsequent management of patients with high-risk disease when PSMA PET/CT is utilised for primary staging.

Experience of use of gallium ($^{68}$Ga) gozetotide PET for selection of patients for PSMA-based therapy is limited to patients with progressive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor (AR) pathway inhibition and taxane-based chemotherapy, and to selection of patients for treatment with lutetium ($^{177}$Lu) vipivotide tetraxetan. Benefit-risk ratio may not be generalisable to other types of PSMA-based therapy and patients with mCRPC with different prior treatments.

Radiation risk

Gallium ($^{68}$Ga) gozetotide contributes to the patient's overall long-term cumulative radiation exposure, which is associated with an increased risk of cancer. Safe handling, reconstitution and radiolabelling procedures should be ensured to protect patients and healthcare professionals from unintentional radiation exposure (see sections 6.6 and 12).

Interpretation of gallium ($^{68}$Ga) gozetotide images

PET images with gallium ($^{68}$Ga) gozetotide should be interpreted by visual assessment. Suspicion of malignant lesions is based on gallium ($^{68}$Ga) gozetotide uptake in comparison with tissue background.

Gallium ($^{68}$Ga) gozetotide uptake is not specific to prostate cancer and may occur in normal tissues (see section 5.2), other types of cancers and non-malignant processes, potentially leading to false positive findings. Moderate to high physiological PSMA uptake is noted in the kidneys, lacrimal glands, liver, salivary glands and urinary bladder wall. False positive findings include, but are not limited to, renal cell carcinoma, hepatocellular carcinoma, breast cancer, lung cancer, benign bone diseases (e.g. Paget's disease), pulmonary sarcoidosis/granulomatosis, gliomas, meningiomas, paragangliomas and neurofibromas. Ganglia can mimic lymph nodes.

The diagnostic performance of gallium ($^{68}$Ga) gozetotide may be affected by serum PSA levels, androgen-receptor-targeting treatments, disease stage and size of malignant lymph nodes (see section 5.1).

Gallium ($^{68}$Ga) gozetotide PET images should be interpreted only by readers trained in the interpretation of PET images with gallium ($^{68}$Ga) gozetotide PET. Findings on gallium ($^{68}$Ga) gozetotide PET images should always be interpreted in conjunction with and be confirmed by other diagnostic methods (including histopathology) before subsequent change in patient management is initiated.

Patient preparation

Patients should be well hydrated prior to gallium ($^{68}$Ga) gozetotide administration and should be advised to void immediately prior to and frequently during the first hours after image acquisition in order to reduce radiation exposure.

Specific warnings

*Sodium content*
This medicinal product contains 28.97 mg sodium per injection, equivalent to 1.5% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

*Acidic pH and extravasation*
Low pH of gallium ($^{68}$Ga) gozetotide may lead to injection site reactions after administration. Accidental extravasation may cause local irritation, due to the acidic pH of the solution. Cases of extravasation should be managed as per institutional guidelines.

## 4.5 Interaction with other medicinal products and other forms of interaction

Based on *in vitro* interaction studies, gallium ($^{68}$Ga) gozetotide is not expected to have any clinically significant interaction with other medicinal products (see section 5.2). No interaction studies have been performed.

## 4.6 Fertility, pregnancy and lactation

Pregnancy

Locametz is not indicated for use in females. There are no data on the use of gallium ($^{68}$Ga) gozetotide in females. Reproductive toxicity studies in animals have not been conducted with gallium ($^{68}$Ga) gozetotide. However, all radiopharmaceuticals, including gallium ($^{68}$Ga) gozetotide, have the potential to cause foetal harm.

Breast-feeding

Locametz is not indicated for use in females. There are no data on the effects of gallium ($^{68}$Ga) gozetotide on the breast-fed newborn/infant or on milk production. Lactation studies have not been conducted in animals with gallium ($^{68}$Ga) gozetotide.

Fertility

There are no data on the effect of gallium ($^{68}$Ga) gozetotide on human fertility.

## 4.7 Effects on ability to drive and use machines

Gallium ($^{68}$Ga) gozetotide has no or negligible influence on the ability to drive and use machines.

## 4.8 Undesirable effects

Summary of safety profile

Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary defects. As the effective dose is 0.0166 mSv/MBq, with a maximal recommended dose of 259 MBq (4.3 mSv), these adverse reactions are expected to occur with a low probability.

Mild to moderate adverse reactions occurred in patients receiving gallium ($^{68}$Ga) gozetotide, with the exception of a grade 3 fatigue event (0.1%).

The most common adverse reactions are fatigue (1.2%), nausea (0.8%), constipation (0.5%) and vomiting (0.5%).

Tabulated list of adverse reactions

The safety profile of gallium ($^{68}$Ga) gozetotide at median dose per body weight of 1.9 MBq/kg (range: 0.9-3.7 MBq/kg) was evaluated in 1 003 patients with metastatic castration-resistant prostate cancer receiving physician's discretion for best standard of care (VISION study).

Adverse reactions (Table 1) are listed by MedDRA system organ class. Within each system organ class, the adverse reactions are ranked by frequency, with the most frequent reactions first. Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness. In addition, the corresponding frequency category for each adverse reaction is based on the following convention (CIOMS III): very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1 000 to <1/100); rare (≥1/10 000 to <1/1 000); very rare (<1/10 000).

**Table 1 Adverse reactions observed with gallium ($^{68}$Ga) gozetotide**

| System organ class | Frequency category | Adverse reaction |
|---|---|---|
| Gastrointestinal disorders | Uncommon | Nausea |
| | Uncommon | Constipation |
| | Uncommon | Vomiting |
| | Uncommon | Diarrhoea |
| | Uncommon | Dry mouth |
| General disorders and administration site conditions | Common | Fatigue |
| | Uncommon | Injection site reactions[1] |
| | Uncommon | Chills |

[1] Injection site reactions includes: injection site haematoma, injection site warmth, injection site pruritus

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.

### 4.9 Overdose

In the event of administration of a radiation overdose with gallium ($^{68}$Ga) gozetotide, the radiation absorbed dose to the patient should be reduced where possible by increasing the elimination of the radionuclide from the body by hydration and frequent bladder voiding. It might be helpful to estimate the effective radiation dose that was applied.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Diagnostic radiopharmaceuticals, other diagnostic radiopharmaceuticals for tumour detection, ATC code: V09IX14

Mechanism of action

Gallium ($^{68}$Ga) gozetotide binds to cells that express PSMA, including malignant prostate cancer cells, which overexpress PSMA. Gallium-68 is a radionuclide with an emission yield that allows PET imaging. Based on the intensity of the signals, PET images obtained with gallium ($^{68}$Ga) gozetotide indicate the presence of PSMA protein in tissues.

Pharmacodynamic effects

At the chemical concentrations used for diagnostic examinations, gallium ($^{68}$Ga) gozetotide does not have any pharmacodynamic activity.

Clinical efficacy and safety

The sensitivity and specificity of gallium ($^{68}$Ga) gozetotide were evaluated in the two following prospective studies:

In van Kalmthout et al, 2020, 103 adult male patients with biopsy-proven prostate cancer and intermediate- and high-risk features indicated for extended pelvic lymph node dissection (ePLND) underwent gallium ($^{68}$Ga) gozetotide PET/CT imaging. PET/CT scans were read by two independent blinded readers and ePLND was the histopathology reference standard for 96 out of 103 (93%) patients. Patient-based sensitivity, specificity, positive and negative predictive value (PPV and NPV, respectively) of gallium ($^{68}$Ga) gozetotide PET/CT imaging to detect lymph node metastasis (LNM) are summarised in Table 2.

**Table 2 Efficacy results in primary staging in patients with biopsy-proven prostate cancer**

| | **Patient-based N=96[1]** |
|---|---|
| Sensitivity (95% CI) | 42% (27, 58) |
| Specificity (95% CI) | 91% (79, 97) |
| PPV | 77% (54, 91) |
| NPV | 68% (56, 78) |

[1] Evaluable population

Inter-reader agreement was $\kappa = 0.67$ for the 2 independent blinded readers. Of the 67 LNM analysed, 26 were detected by gallium ($^{68}$Ga) gozetotide PET/CT, resulting in 38.8% node-based sensitivity. Median diameter of the metastatic deposit in these detected LNM was 7 mm (range: 0.3-35). The PET reading missed 41 LNM with a median metastatic deposit of 3.0 mm (range: 0.5 to 35.0).

In Fendler et al, 2019, 635 adult male patients with histopathology-proven and biochemical recurrence (BCR) prostate cancer after prostatectomy (N=262), radiation therapy (N=169) or both (N=204) underwent gallium ($^{68}$Ga) gozetotide PET/CT or PET/MRI imaging. BCR was defined by serum PSA of ≥0.2 ng/mL more than 6 weeks after prostatectomy or by an increase in serum PSA of at least 2 ng/mL above nadir after definitive radiotherapy. Patients had median PSA level of 2.1 ng/mL above nadir after radiation therapy (range: 0.1-1 154 ng/mL). A composite reference standard, including histopathology, serial serum PSA levels and imaging (CT, MRI, and/or bone scan) findings was available for 223 of 635 (35.1%) patients, while histopathology reference standard alone was available for 93 (14.6%) patients. PET/CT scans were read by 3 independent readers blinded to clinical information other than the type of primary therapy and most recent serum PSA level.

Detection of PSMA-positive lesions occurred in 475 of 635 (75%) patients receiving gallium ($^{68}$Ga) gozetotide and the detection rate was significantly increased with PSA levels. The detection rate of gallium ($^{68}$Ga) gozetotide PET positive lesion increased with increasing serum PSA levels (see section 4.4). Sensitivity and positive predictive value (PPV) of gallium ($^{68}$Ga) gozetotide PET/CT imaging are summarised in Table 3. Inter-reader Fleiss κ for gallium ($^{68}$Ga) gozetotide PET/CT imaging ranged from 0.65 (95% CI: 0.61, 0.70) to 0.78 (95% CI: 0.73, 0.82) across the assessed regions (prostate bed, pelvic nodes, extrapelvic soft tissues and bones).

**Table 3 Efficacy results in patients with histopathology-proven and BCR prostate cancer**

| | **Composite reference standard N=223[1]** | **Histopathology reference standard N=93[1]** |
|---|---|---|
| Sensitivity per-patient (95% CI) | NA | 92% (84, 96) |
| Sensitivity per-region (95% CI) | NA | 90% (82, 95) |
| PPV per-patient (95% CI) | 92% (88, 95) | 84% (75, 90) |
| PPV per-region (95% CI) | 92% (88, 95) | 84% (76, 91) |
| [1] Evaluable population | | |

Gallium ($^{68}$Ga) gozetotide PET/CT imaging was used to identify adult patients with progressive, PSMA-positive mCRPC cancer for the randomised, multicentre, open-label, phase III study VISION, which tested efficacy of Pluvicto plus best standard of care or best standard of care alone. A total of 1 003 male patients, who had been treated with at least one androgen receptor (AR) pathway inhibitor and 1 or 2 prior taxane-based chemotherapy regimens, were selected based on the PSMA expression of their prostate cancer lesions. Patients underwent a gallium ($^{68}$Ga) gozetotide PET/CT scan to evaluate PSMA expression in lesions defined by central read criteria. Improved overall survival and radiographic progression-free survival were reported in the PSMA-targeted therapy arm.

Paediatric population

The European Medicines Agency has waived the obligation to submit the results of studies with Locametz in all subsets of the paediatric population for visualisation of PSMA in prostate cancer (see section 4.2 for information on paediatric use).

## 5.2 Pharmacokinetic properties

Distribution

Gallium ($^{68}$Ga) gozetotide exhibits bi-exponential behaviour in blood, with a biological half-life of 6.5 minutes for the fast component and a terminal half-life of 4.4 hours for the slower component. Based on *in vitro* data, gozetotide mainly distributes to plasma, with a mean blood-to-plasma ratio of 0.71. Gozetotide is 33% bound to human plasma proteins.

Organ uptake

The highest radiation absorbed dose of gallium ($^{68}$Ga) gozetotide occurred in the kidneys, lacrimal glands, salivary glands, urinary bladder wall and liver.

The estimated radiation absorbed doses to these organs for an administered activity of 259 MBq are 62.1 mGy (kidneys), 28.5 mGy (lacrimal glands), 23.1 mGy (salivary glands), 14.8 mGy (urinary bladder wall) and 13.7 mGy (liver).

Biotransformation

Based on *in vitro* data, gallium ($^{68}$Ga) gozetotide undergoes negligible hepatic and renal metabolism.

Elimination

Gallium ($^{68}$Ga) gozetotide is mainly eliminated via the renal route. Approximately 14% of the gallium ($^{68}$Ga) gozetotide dose administered is excreted in the urine after 2 hours post-injection.

Half-life

Based on the gallium ($^{68}$Ga) gozetotide biological and terminal half-life of 4.4 hours and on the gallium-68 physical half-life of 68 minutes, the resulting gallium ($^{68}$Ga) gozetotide effective half-life is 54 minutes.

*In vitro* evaluation of drug interaction potential

*CYP450 enzymes*
Gozetotide is not a substrate, inhibitor or inducer of cytochrome P450 (CYP450) enzymes. Gallium ($^{68}$Ga) gozetotide is not expected to have any drug interactions with CYP450 substrates, inhibitors or inducers.

*Transporters*
Gozetotide is not a substrate of BCRP, P-gp, MATE1, MATE2-K, OAT1, OAT3 or OCT2. Gozetotide is not an inhibitor of BCRP, BSEP, P-gp, MATE1, MATE2-K, OAT1, OAT3, OATP1B1, OATP1B3, OCT1 or OCT2. Gallium ($^{68}$Ga) gozetotide is not expected to have any drug interactions with the substrates of these transporters.

Special populations

*Elderly*
In the VISION clinical study, 752 of 1 003 (75%) patients were aged 65 years or older. No overall differences in safety and efficacy were observed between these patients and younger patients.

*Renal impairment / hepatic impairment*
Gallium ($^{68}$Ga) gozetotide pharmacokinetics and biodistribution are not expected to be affected by renal/hepatic impairment to any clinically relevant extent.

### 5.3 Preclinical safety data

Gozetotide was evaluated in safety pharmacology and single-dose toxicity studies. Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology and single-dose toxicity.

Carcinogenicity and mutagenicity

Mutagenicity studies and carcinogenicity studies have not been carried out with gallium ($^{68}$Ga) gozetotide.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Gentisic acid
Sodium acetate trihydrate
Sodium chloride

### 6.2 Incompatibilities

This medicinal product must not be mixed with other medicinal products except those mentioned in sections 6.6 and 12.

### 6.3 Shelf life

Unopened vial: 1 year.

After reconstitution and radiolabelling, chemical and physical in-use stability have been demonstrated for 6 hours at 30°C (see section 6.4). Store upright.

From a microbiological point of view, unless the method of opening, reconstitution, radiolabelling, or dilution precludes the risk of microbial contamination, the product should be used immediately.

If not used immediately, in-use storage times and conditions are the responsibility of the user.

## 6.4 Special precautions for storage

Before reconstitution, store below 25°C.

For storage conditions after reconstitution and radiolabelling of the medicinal product, see section 6.3.

Storage of radiopharmaceuticals should be in accordance with national regulations on radioactive materials.

## 6.5 Nature and contents of container

Locametz is supplied as a multidose kit for the radiopharmaceutical preparation of gallium ($^{68}$Ga) gozetotide solution for injection (see sections 2 and 3). Locametz contains one 10 mL type I Plus glass vial closed with a rubber stopper and sealed with a flip-off cap.

## 6.6 Special precautions for disposal and other handling

General warning

Radiopharmaceuticals should be received, used and administered only by authorised persons in designated clinical settings. Their receipt, storage, use, transfer and disposal are subject to the regulations and/or appropriate licences of the competent official organisation.

Radiopharmaceuticals should be prepared in a manner which satisfies both radiation safety and pharmaceutical quality requirements. Appropriate aseptic precautions should be taken.

The content of the vial is intended only for use in the preparation of gallium ($^{68}$Ga) gozetotide solution for injection and is not to be administered directly to the patient without first undergoing the preparative procedure (see sections 4.2 and 12).

Precautions to be taken before handling or administration of the medicinal product

Before reconstitution, the content of Locametz is not radioactive. After reconstitution and radiolabelling, effective radiation shielding of the gallium ($^{68}$Ga) gozetotide solution for injection must be maintained (see section 3).

After reconstitution and radiolabelling, Locametz contains a sterile solution for injection of gallium ($^{68}$Ga) gozetotide at an activity of up to 1 369 MBq. The gallium ($^{68}$Ga) gozetotide solution for injection also contains hydrochloric acid derived from the gallium-68 chloride solution.

Gallium ($^{68}$Ga) gozetotide solution for injection is a sterile, clear, colourless solution for intravenous administration, without undissolved matter and with pH between 3.2 to 6.5.

Appropriate aseptic precautions should be taken when withdrawing and administering gallium ($^{68}$Ga) gozetotide solution for injection.

Administration procedures should be carried out in a way to minimise risk of contamination of the medicinal product and irradiation of the operators. Effective radiation shielding is mandatory.

If at any time in the preparation of this medicinal product the integrity of the vial is compromised it should not be used.

For instructions on reconstitution and radiolabelling of the medicinal product before administration, see section 12.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

## 7. MARKETING AUTHORISATION HOLDER

Novartis Europharm Limited
Vista Building
Elm Park, Merrion Road
Dublin 4
Ireland

## 8. MARKETING AUTHORISATION NUMBER(S)

EU/1/22/1692/001

## 9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

09 December 2022

## 10. DATE OF REVISION OF THE TEXT

## 11. DOSIMETRY

Gallium-68 is produced by means of a germanium-68/gallium-68 ($^{68}$Ge/$^{68}$Ga) generator and decays with a half-life of 68 min to stable zinc-68. Gallium-68 decays as follows:

- 89% through positron emission with a mean energy of 836 keV, followed by photonic annihilation radiations of 511 keV (178%).
- 10% through orbital electron capture (X-ray or Auger emissions), and
- 3% through 13 gamma transitions from 5 excited levels.

The effective radiation dose of gallium ($^{68}$Ga) gozetotide is 0.022 mSv/MBq, resulting in an approximate effective radiation dose of 5.70 mSv for an administered maximum activity of 259 MBq.

Median radiation absorbed doses for organs and tissues of adult patients (N=6) following intravenous injection of gallium ($^{68}$Ga) gozetotide including observed ranges were calculated by Sandgren et al, 2019, using ICRP/ICRU voxel phantom with the software IDAC-Dose 2.1. Median radiation absorbed doses of gallium ($^{68}$Ga) gozetotide are shown in Table 4.

**Table 4 Estimated median radiation absorbed doses of gallium ($^{68}$Ga) gozetotide**

| | Radiation absorbed dose (mGy/MBq)[1] N=6 | |
|---|---|---|
| **Organ** | **Median (mGy/MBq)** | **Range (mGy/MBq)** |
| Adrenals | 0.048 | 0.0405 – 0.0548 |
| Brain | 0.008 | 0.0065 – 0.0079 |
| Breast | 0.008 | 0.0077 – 0.0087 |
| Endosteum (bone surface)* | 0.011 | 0.0095 – 0.0110 |
| Eye lenses* | 0.0051 | 0.0047 – 0.0054 |
| Gallbladder wall | 0.027 | 0.0212 – 0.0343 |
| Heart wall | 0.026 | 0.0236 – 0.0317 |
| Kidneys* | 0.240 | 0.2000 – 0.2800 |
| Lacrimal glands* | 0.110 | 0.0430 – 0.2000 |
| Left colon wall** | 0.014 | 0.0120 – 0.0140 |
| Liver* | 0.053 | 0.0380 – 0.0710 |
| Lungs* | 0.016 | 0.0130 – 0.0170 |
| Muscle | 0.0083 | 0.0073 – 0.0086 |
| Oesophagus* | 0.014 | 0.0110 – 0.0150 |
| Pancreas | 0.019 | 0.0173 – 0.0209 |
| Recto-sigmoid colon wall | 0.013 | 0.0108 – 0.0149 |
| Red (active) bone marrow* | 0.015 | 0.0140 – 0.0150 |
| Right colon wall** | 0.014 | 0.0120 – 0.0140 |
| Salivary glands* | 0.089 | 0.0740 – 0.1500 |
| Skin* | 0.007 | 0.0059 – 0.0069 |
| Small intestine wall | 0.014 | 0.0129 – 0.0149 |
| Spleen* | 0.046 | 0.0300 – 0.1000 |
| Stomach wall* | 0.015 | 0.0150 – 0.0170 |
| Testes* | 0.009 | 0.0074 – 0.0089 |
| Thymus | 0.0081 | 0.0072 – 0.0085 |
| Thyroid* | 0.010 | 0.0090 – 0.0100 |
| Urinary bladder wall* | 0.057 | 0.0280 – 0.0840 |
| Effective dose (mSv/MBq)*[2] | 0.022 | 0.0204 – 0.0242 |

* as reported by Sandgren et al, 2019; all other organ estimates were estimated based on the time-integrated activity coefficients of the source organs published in the paper

** reported in Sandgren as a single value labelled "Colon"

[1] doses were calculated using the software IDAC-Dose 2.1.

[2] derived according to ICRP Publication 103

## 12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Method of preparation

*Step 1: Reconstitution and radiolabelling*

Locametz allows the direct preparation of gallium ($^{68}$Ga) gozetotide solution for injection with the eluate from one of the following generators (see below for specific instructions for use with each generator):

- Eckert & Ziegler GalliaPharm germanium-68/gallium-68 ($^{68}$Ge/$^{68}$Ga) generator
- IRE ELiT Galli Ad germanium-68/gallium-68 ($^{68}$Ge/$^{68}$Ga) generator

The instructions for use provided by the germanium-68/gallium-68 generator manufacturer should also be followed.

Gallium ($^{68}$Ga) gozetotide solution for injection should be prepared according to the following aseptic procedure:

a. Flip the cap off the Locametz vial and swab the septum with an appropriate antiseptic, then allow the septum to dry.
b. Pierce the Locametz vial septum with a sterile needle connected to a 0.2 micron sterile air venting filter to maintain atmospheric pressure within the vial during the reconstitution process. Place the Locametz vial in a lead shield container.

Follow the generator-specific reconstitution and radiolabelling procedures as shown in Table 5 and in Figures 1 and 2. Then continue with Step 2.

**Table 5 Reconstitution and radiolabelling with Eckert & Ziegler GalliaPharm and IRE ELiT Galli Ad generators**

| **If Eckert & Ziegler GalliaPharm generator is used** | **If IRE ELiT Galli Ad generator is used** |
|---|---|
| • Connect the male luer of the outlet line of the generator to a sterile elution needle (size 21G-23G).<br>• Connect the Locametz vial directly to the outlet line of the generator by pushing the elution needle through the rubber septum.<br>• Elute directly from the generator into the Locametz vial. | |
| Perform the elution manually or by means of a pump according to the generator instructions for use. | Connect the Locametz vial through the vent needle with 0.2 micron sterile air venting filter to a vacuum vial (25 mL minimum volume) by means of a sterile needle (size 21G-23G) or to a pump to start the elution. |
| Reconstitute the lyophilised powder with 5 mL of eluate. | Reconstitute the lyophilised powder with 1.1 mL of eluate. |
| At the end of the elution, disconnect the Locametz vial from the generator by removing the elution needle and the vent needle with the 0.2 micron sterile air venting filter from the rubber septum. Then, invert the Locametz vial once and place it upright. | At the end of the elution, first withdraw the sterile needle from the vacuum vial or disconnect the vacuum pump in order to establish atmospheric pressure into the Locametz vial, then disconnect the vial from the generator by removing both the elution needle and the vent needle with the 0.2 micron sterile air venting filter needle from the rubber septum. |

**Figure 1 Reconstitution and radiolabelling procedure for Eckert & Ziegler GalliaPharm generator**

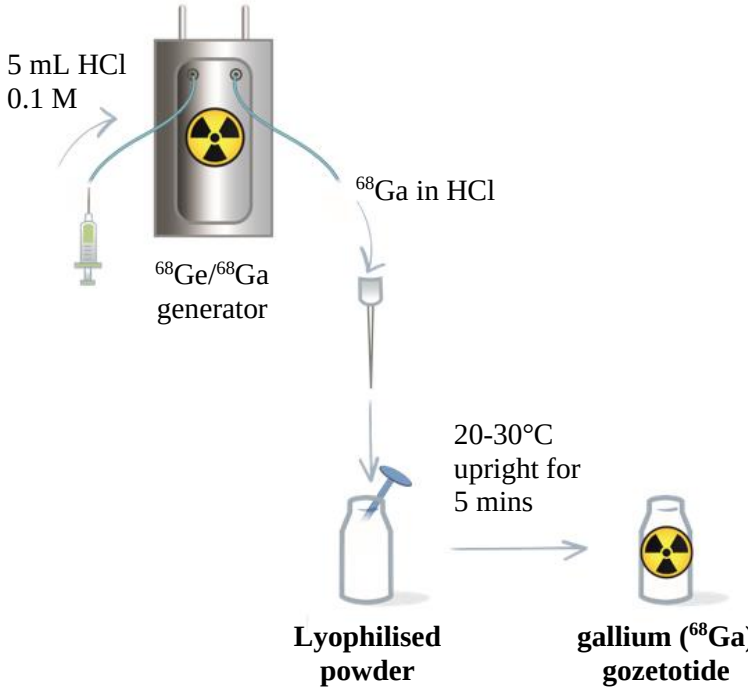
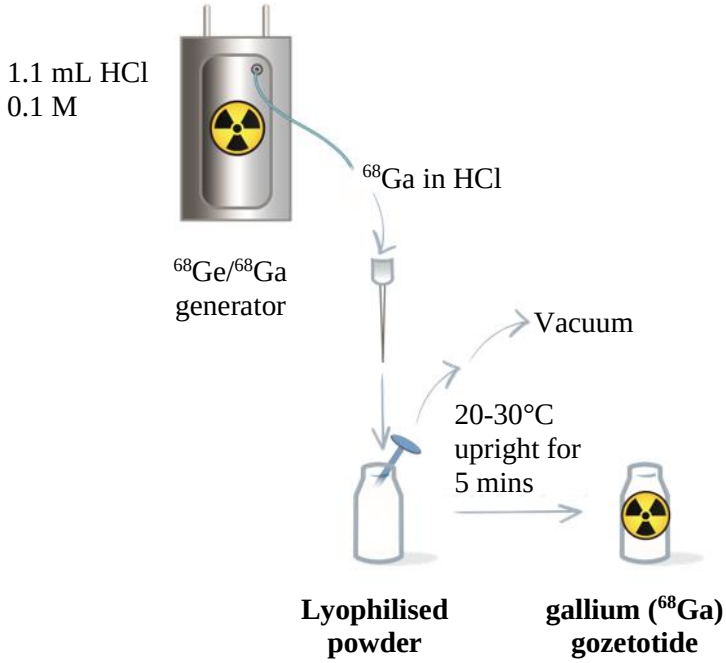



**Figure 2 Reconstitution and radiolabelling procedure for IRE ELiT Galli Ad generator**




*Step 2: Incubation*

a. Incubate the Locametz vial upright at room temperature (20-30°C) for at least 5 minutes without agitation or stirring.
b. After 5 minutes, assay the vial containing the gallium ($^{68}$Ga) gozetotide solution for injection for total radioactivity concentration using a dose calibrator and record the result.
c. Perform quality controls according to the recommended methods in order to check compliance with the specifications (see Step 3).
d. Store the Locametz vial containing the gallium ($^{68}$Ga) gozetotide solution for injection upright in a lead shield container below 30°C until use.

e. After addition of gallium-68 chloride to the Locametz vial, use gallium ($^{68}$Ga) gozetotide solution for injection within 6 hours.

*Step 3: Specifications and quality control*
Perform the quality controls in Table 6 behind a lead glass shield for radioprotection purposes.

**Table 6 Specifications of the gallium (68Ga) gozetotide solution for injection**

| Test | Acceptance criteria | Method |
|---|---|---|
| **Appearance** | Clear, colourless and without undissolved matter | Visual inspection |
| **pH** | 3.2 – 6.5 | pH-indicator strips |
| **Labelling efficiency** | Non-complexed gallium-68 species ≤3% | Instant thin layer chromatography (ITLC, see details below) |

Determine labelling efficiency of gallium ($^{68}$Ga) gozetotide solution for injection by performing instant thin layer chromatography (ITLC).
Perform ITLC using ITLC SG strips and using ammonium acetate 1M: Methanol (1:1 V/V) as mobile phase.

*ITLC method*
a. Develop the ITLC SG strip for a distance of 6 cm from the point of application (i.e. to 7 cm from the bottom of the ITLC strip).
b. Scan the ITLC SG strip with a radiometric ITLC scanner.
c. Calculate labelling efficiency by integration of the peaks on the chromatogram. Do not use the reconstituted and radiolabelled product if the percentage (%) of non-complexed gallium-68 species is higher than 3%.

The retention factor (Rf) specifications are as follows:
- Non-complexed gallium-68 species, Rf = 0 to 0.2;
- Gallium ($^{68}$Ga) gozetotide, Rf = 0.8 to 1

*Step 4: Administration*
a. Aseptic technique and radiation shielding should be used when withdrawing and administering gallium ($^{68}$Ga) gozetotide solution for injection (see sections 4.2 and 6.6).
b. Prior to use, visually inspect the prepared gallium ($^{68}$Ga) gozetotide solution for injection behind a lead glass shield for radioprotection purposes. Only solutions that are clear, colourless and without undissolved matter should be used (see sections 4.2 and 6.6).
c. After reconstitution and radiolabelling, gallium ($^{68}$Ga) gozetotide solution for injection can be diluted with water for injections or sodium chloride 9 mg/mL (0.9%) solution for infusion up to a final volume of 10 mL. For the IRE ELiT Galli Ad generator, dilution to a minimum volume of 4 mL is required in order to reduce osmolality.
d. Using a single-dose syringe fitted with a sterile needle (size 21G-23G) and protective shielding, aseptically withdraw the prepared gallium ($^{68}$Ga) gozetotide solution for injection prior to administration (see sections 4.2 and 6.6).
e. The total radioactivity in the syringe should be verified with a dose calibrator immediately before and after gallium ($^{68}$Ga) gozetotide administration to the patient. The dose calibrator must be calibrated and comply with international standards (see section 4.2).

Detailed information on this medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu.

# ANNEX II

**A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE**

**B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**

**C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION**

**D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT**

## A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

Advanced Accelerator Applications (Italy) S.R.L.
Via Crescentino snc
13040 Saluggia (VC)
Italy

## B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Medicinal product subject to restricted medical prescription (see Annex I: Summary of Product Characteristics, section 4.2).

## C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

- **Periodic safety update reports (PSURs)**

The requirements for submission of PSURs for this medicinal product are set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and any subsequent updates published on the European medicines web-portal.

The marketing authorisation holder (MAH) shall submit the first PSUR for this product within 6 months following authorisation.

## D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

- **Risk management plan (RMP)**

The marketing authorisation holder (MAH) shall perform the required pharmacovigilance activities and interventions detailed in the agreed RMP presented in Module 1.8.2 of the marketing authorisation and any agreed subsequent updates of the RMP.

An updated RMP should be submitted:
- At the request of the European Medicines Agency;
- Whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important (pharmacovigilance or risk minimisation) milestone being reached.

**ANNEX III**

**LABELLING AND PACKAGE LEAFLET**

# A. LABELLING

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

**OUTER CARTON**

## 1. NAME OF THE MEDICINAL PRODUCT

Locametz 25 micrograms kit for radiopharmaceutical preparation
gozetotide

## 2. STATEMENT OF ACTIVE SUBSTANCE(S)

The vial contains 25 micrograms of gozetotide.

## 3. LIST OF EXCIPIENTS

Sodium chloride, gentisic acid, sodium acetate trihydrate. See package leaflet for further information.

## 4. PHARMACEUTICAL FORM AND CONTENTS

Kit for radiopharmaceutical preparation

1 vial.

## 5. METHOD AND ROUTE(S) OF ADMINISTRATION

For multidose use.
To be reconstituted and radiolabelled with gallium-68 chloride solution provided by a germanium-68/gallium-68 generator.
Read the package leaflet before use.
Intravenous use after reconstitution and radiolabelling.

## 6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

## 7. OTHER SPECIAL WARNING(S), IF NECESSARY

Medicinal product radioactive after reconstitution.

## 8. EXPIRY DATE

EXP
After reconstitution and radiolabelling, store upright below 30°C and use within 6 hours.

## 9. SPECIAL STORAGE CONDITIONS

Before reconstitution, store below 25°C.

## 10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

## 11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Novartis Europharm Limited
Vista Building
Elm Park, Merrion Road
Dublin 4
Ireland

## 12. MARKETING AUTHORISATION NUMBER(S)

EU/1/22/1692/001

## 13. BATCH NUMBER

Lot

## 14. GENERAL CLASSIFICATION FOR SUPPLY

## 15. INSTRUCTIONS ON USE

## 16. INFORMATION IN BRAILLE

Justification for not including Braille accepted.

## 17. UNIQUE IDENTIFIER – 2D BARCODE

Not applicable.

## 18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

Not applicable.

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**POWDER VIAL**

## 1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Locametz 25 mcg kit for radiopharmaceutical preparation
gozetotide
Intravenous use after reconstitution and radiolabelling

## 2. METHOD OF ADMINISTRATION

To be reconstituted and radiolabelled with gallium-68 chloride solution provided by a germanium-68/gallium-68 generator.
Read the package leaflet before use.

## 3. EXPIRY DATE

EXP

## 4. BATCH NUMBER

Lot

## 5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

25 mcg

## 6. OTHER

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**SHIELD LABEL TO BE APPLIED AFTER RADIOLABELLING**

## 1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Locametz 25 micrograms
gallium ($^{68}$Ga) gozetotide solution for injection
Intravenous use

## 2. METHOD OF ADMINISTRATION

Read the package leaflet before use.

## 3. EXPIRY DATE

EXP____ Time/Date

After radiolabelling, use within 6 hours.

## 4. BATCH NUMBER

Lot

## 5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

Total activity: _____MBq
Total volume: _____mL
Calibration time: _____ Time/Date

## 6. OTHER

Store upright below 30°C.

Radioactive imaging agent

# B. PACKAGE LEAFLET

**Package leaflet: Information for the patient**

**Locametz 25 micrograms kit for radiopharmaceutical preparation**
gozetotide

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

**Read all of this leaflet carefully before you are given this medicine because it contains important information for you.**
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your nuclear medicine doctor who will supervise the procedure.
- If you get any side effects, talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**



## 1. What Locametz is and what it is used for

**What Locametz is**
This medicine is a radiopharmaceutical product for diagnostic use only.

Locametz contains a substance called gozetotide. Before use, gozetotide (the powder in the vial) is coupled with a radioactive substance called gallium-68 to make gallium ($^{68}$Ga) gozetotide solution (this procedure is called radiolabelling).

**What Locametz is used for**
After radiolabelling with gallium-68, Locametz is used in a medical imaging procedure called positron emission tomography (PET) to detect specific types of cancer cells with a protein called prostate-specific membrane antigen (PSMA) in adults with prostate cancer. This is done:
- to find out whether prostate cancer has spread to lymph nodes and other tissues outside the prostate, before primary curative therapy (e.g. therapy involving surgical removal of the prostate, radiation therapy)
- to identify cancer cells when recurrence of prostate cancer is suspected in patients who have received primary curative therapy
- to find out whether patients with progressive metastatic castration-resistant prostate cancer may be suitable for a specific therapy, called PSMA-targeted therapy

**How Locametz works**
When given to the patient, gallium ($^{68}$Ga) gozetotide binds to the cancer cells that have PSMA on their surface and makes them visible to your nuclear medicine doctor during the PET medical imaging procedure. This gives your doctor and nuclear medicine doctor valuable information about your disease.

The use of gallium ($^{68}$Ga) gozetotide involves exposure to a small amount of radioactivity. Your doctor and the nuclear medicine doctor have considered that the clinical benefit that you will obtain from the procedure with the radiopharmaceutical outweighs the risk due to radiation.

If you have any questions about how Locametz works or why this medicine has been prescribed for you, ask your nuclear medicine doctor.

## 2. What you need to know before Locametz is used

**Locametz must not be used**
- if you are allergic to gozetotide or any of the other ingredients of this medicine (listed in section 6).

**Warnings and precautions**
Talk to your nuclear medicine doctor before you receive Locametz if you have any other type of cancer, as this could affect the interpretation of the image.

The use of Locametz involves exposure to a small amount of radioactivity. Repeated exposure to radiation may increase the risk of cancer. Your nuclear medicine doctor will explain necessary radioprotection measures to you (see section 3).

**Before administration of Locametz you should**
- Drink plenty of water so that you remain hydrated and urinate immediately before the PET medical imaging procedure, and as often as possible during the first hours after administration.

**Children and adolescents**
This medicine should not be given to children or adolescents aged under 18 years because no data are available in this age group.

**Pregnancy and breast-feeding**
Locametz is not intended for use in women. All radiopharmaceuticals, including Locametz, have the potential to cause harm to an unborn baby.

**Driving and using machines**
It is considered unlikely that Locametz will affect your ability to drive or to use machines.

**Locametz contains sodium**
This medicine contains 28.97 mg sodium (main component of cooking/table salt) in each injection. This is equivalent to 1.5% of the recommended maximum daily dietary intake of sodium for an adult.

## 3. How Locametz is used

There are strict laws on the use, handling and disposal of radiopharmaceutical products. Locametz will only be used in special controlled areas. This radiopharmaceutical product will only be handled and given to you by people who are trained and qualified to use it safely. These persons will take special care for the safe use of this radiopharmaceutical product and will keep you informed of their actions.

The nuclear medicine doctor supervising the procedure will decide on the quantity of Locametz to be used in your case. It will be the smallest quantity necessary to get the desired information.

The quantity to be administered usually recommended for an adult is 1.8-2.2 MBq (megabecquerel, the unit used to express radioactivity) per kg of body weight, with a minimum amount of 111 MBq and a maximum of 259 MBq.

**Administration of Locametz and conduct of the procedure**
After reconstitution and radiolabelling, Locametz is given as a slow injection into a vein. You will undergo a PET scan starting 50 to 100 minutes after you have received Locametz.

**Duration of the procedure**
Your nuclear medicine doctor will inform you about the usual duration of the procedure.

**After administration of Locametz, you should**
- Continue to drink plenty of water so that you remain hydrated and urinate as often as possible to eliminate the radiopharmaceutical product from your body.

The nuclear medicine doctor will inform you if you need to take any special precautions after receiving this medicine. Contact your nuclear medicine doctor if you have any questions.

**If you have been given more Locametz than you should**
An overdose of Locametz is unlikely because you will only receive a single dose that is precisely controlled by the nuclear medicine doctor supervising the procedure. However, in the event of an overdose, you will receive the appropriate treatment. You may be asked to drink and urinate frequently in order to eliminate the radiopharmaceutical product from your body.

Should you have any further question on the use of Locametz, please ask the nuclear medicine doctor who supervises the procedure.

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Side effects include the following listed below. If these side effects become severe, please tell your nuclear medicine doctor.

**Common** (may affect up to 1 in every 10 people)
- tiredness (fatigue)

**Uncommon** (may affect up to 1 in every 100 people)
- nausea
- constipation
- vomiting
- diarrhoea
- dry mouth
- reactions at the site of injection, such as bruising, itching and warmth (injection site reactions)
- chills

This radiopharmaceutical product will deliver low amounts of ionising radiation associated with the least risk of cancer and hereditary abnormalities.

**Reporting of side effects**
If you get any side effects, talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How Locametz is stored

You will not have to store this medicine. This medicine is stored under the responsibility of the specialist in appropriate premises. Storage of radiopharmaceutical products will be in accordance with national regulations on radioactive materials.

The following information is intended for the specialist only:
- Locametz must not be used after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of that month.
- Before reconstitution, store below 25°C.
- After reconstitution and radiolabelling, store upright below 30°C. Use within 6 hours.

## 6. Contents of the pack and other information

**What Locametz contains**
- The active substance is gozetotide. One vial contains 25 micrograms of gozetotide. The other ingredients are: gentisic acid, sodium acetate trihydrate and sodium chloride (see "Locametz contains sodium" in section 2).

**What Locametz looks like and contents of the pack**
Locametz is a multidose kit for radiopharmaceutical preparation containing one vial of white freeze-dried powder (powder for solution for injection).

Gallium-68 is not part of the kit.

After reconstitution and radiolabelling, Locametz contains a sterile solution for injection of gallium ($^{68}$Ga) gozetotide at an activity of up to 1 369 MBq.

After reconstitution, the gallium ($^{68}$Ga) gozetotide solution for injection also contains hydrochloric acid.

Pack size: 1 vial.

**Marketing Authorisation Holder**
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**Manufacturer**
Advanced Accelerator Applications (Italy) S.R.L.
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**This leaflet was last revised in**

**Other sources of information**

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.

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The following information is intended for healthcare professionals only:

The complete SmPC of Locametz is provided as a separate document in the product package, with the objective to provide healthcare professionals with other additional scientific and practical information about the administration and use of this radiopharmaceutical.

Please refer to the SmPC.