LOCAMETZ®
Kit for the preparation of gallium Ga 68 gozetotide
INJECTION FOR INTRAVENOUS USE

Gallium Ga 68 gozetotide PSMA PET imaging for patients with prostate cancer

Indication

LOCAMETZ® (kit for the preparation of gallium Ga 68 gozetotide injection), after radiolabeling with gallium-68, is indicated for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA)-positive lesions in men with prostate cancer:

- with suspected metastasis who are candidates for initial definitive therapy
- with suspected recurrence based on elevated serum prostate-specific antigen (PSA) level
- for selection of patients who are indicated for PSMA-directed therapy as described in the prescribing information of the therapeutic products.

IMPORTANT SAFETY INFORMATION

Risk for Misinterpretation

Image interpretation errors can occur with LOCAMETZ PET. Negative imaging does not rule out the presence of prostate cancer and a positive imaging does not confirm the presence of prostate cancer. Gallium Ga 68 gozetotide uptake is not specific for prostate cancer and may occur with other types of cancer as well as nonmalignant processes. Clinical correlation, which may include histopathological evaluation of the suspected prostate cancer site, is recommended.

Please see additional Important Safety Information throughout and on page 13 and full Prescribing Information.

PSMA is a biomarker in prostate cancer[1-4]

What makes PSMA an ideal target for imaging and treatment?

PSMA CHARACTERISTIC	WHAT IT MEANS
PSMA is overexpressed on prostate cancer (PC) cells in >80% of men with PC[5-9]	Serves as an actionable biomarker, providing an accessible target for ligand binding[5-9]
Ligands are internalized after binding with PSMA and undergo endocytic recycling[2,3]	Facilitates uptake of gallium 68 in PSMA+ cells, including tumor cells[2,3]
PSMA is not appreciably released into circulation even in patients with progressive disease[10]	Facilitates highly specific targeting of PSMA+ lesions[10]

PSMA+, PSMA positive.

PSMA PET imaging using gallium Ga 68 gozetotide has been studied in multiple trials and is approved for patients with prostate cancer[11-16]

- For selection of patients who are indicated for PSMA-directed therapy as described in the prescribing information of the therapeutic products[15]
- For patients with suspected metastasis who are candidates for initial definitive therapy[15]
- For patients with suspected recurrence based on elevated serum PSA level[15]

PET, positron emission tomography.

IMPORTANT SAFETY INFORMATION (continued)

Risk for Misinterpretation (continued)

The performance of LOCAMETZ® (kit for the preparation of gallium Ga 68 gozetotide injection) seems to be affected by serum PSA levels and by site of disease for imaging of biochemically recurrent prostate cancer, and by Gleason score for imaging of metastatic pelvic lymph nodes prior to initial definitive therapy.

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Metastatic PC: Patient selection for PSMA-directed therapy

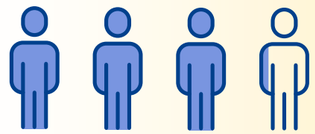
PSMA PET/CT confirmed patient eligibility for PSMA-directed therapy in the phase 3 VISION trial[16]

Outcomes support gallium Ga 68 gozetotide PSMA PET/CT imaging as a method to select patients who may be eligible for PSMA-directed therapy

VISION study design

- The efficacy of LOCAMETZ® (kit for the preparation of gallium Ga 68 gozetotide injection) for selecting patients for PSMA-directed therapy was established in the randomized, multicenter, open-label, phase 3 VISION study and the VISION reader substudy that evaluated imaging interpretation agreement
- Using PSMA PET/CT with gallium Ga 68 gozetotide, 831* of 1003 patients were identified as eligible for the study and then randomized 2:1 to receive either lutetium Lu 177 vipivotide tetraxetan plus BSOC (n=551) or BSOC alone (n=280)

Based on the PSMA expression of their prostate cancer lesions:



831* of 1003

patients were identified as eligible for the VISION study

Consider a PSMA PET/CT scan to select patients with metastatic prostate cancer for whom lutetium Lu 177 vipivotide tetraxetan PSMA-directed therapy is indicated.

BSOC, best standard of care; CT, computed tomography.

*The eligibility criteria for PSMA imaging were met in 869 patients; 831 were judged to have met all the trial eligibility criteria, including the PSMA imaging criteria, and were randomized 2:1 to each study arm.

IMPORTANT SAFETY INFORMATION (continued)

Radiation Risk

Gallium Ga 68 gozetotide contributes to a patient's long-term cumulative radiation exposure, which is associated with an increased risk of cancer. Ensure safe handling to minimize radiation exposure to the patient and health care workers. Advise patients to be well hydrated prior to gallium Ga 68 gozetotide administration and to void immediately prior to and frequently during the first hours after image acquisition to reduce radiation exposure.

PC with suspected metastasis: Before initial definitive therapy

The receptor-based approach of PSMA PET imaging demonstrated strong predictive value when compared against histopathology[15]

The efficacy of LOCAMETZ® (kit for the preparation of gallium Ga 68 gozetotide injection) in men with suspected metastasis who are candidates for initial definitive therapy has been established based on a study of another formulation of gallium Ga 68 gozetotide

- PSMA-PreRP was an open-label, prospective, 2-center study of 325 patients with biopsy-proven prostate cancer who were considered candidates for prostatectomy and pelvic lymph node dissection
- Each patient received a single gallium Ga 68 gozetotide PET/CT or PET/MRI from mid-thigh to skull base
- For each patient, gallium Ga 68 gozetotide PET results and reference standard histopathology obtained from dissected pelvic lymph nodes were compared by region (left hemipelvis, right hemipelvis, and other)

Compared with reference standard histopathology, PSMA PET imaging demonstrated:

61%	**84%**
Positive predictive value (95% CI, 41%-81%)	Negative predictive value (95% CI, 79%-91%)

For patients with suspected metastasis who are candidates for initial definitive therapy, consider a PSMA PET/CT scan if you see[a]:

- Serum PSA of at least 10 ng/mL
- Gleason score >6
- Tumor stage cT2b or greater

MRI, magnetic resonance imaging.
[a] Based on inclusion criteria for the PSMA-PreRP study. Institutional guidelines may vary.

IMPORTANT SAFETY INFORMATION (continued)

Adverse Reactions

Adverse reactions ≥0.5% in the VISION study were fatigue (1.2%), nausea (0.8%), constipation (0.5%), and vomiting (0.5%). Adverse reactions occurring at a rate of <0.5% were diarrhea, dry mouth, injection site reactions, and chills.

Please see additional Important Safety Information throughout and on page 13 and full Prescribing Information.

PC: Suspected biochemical recurrence

>9 of 10 evaluable patients with evidence of biochemical recurrence were found to be true positive after PSMA PET imaging[15]

The efficacy of LOCAMETZ in men with suspected recurrence based on elevated serum PSA level has been established based on studies of another formulation of gallium Ga 68 gozetotide

- PSMA-BCR was an open-label, 2-center prospective study of patients who had biochemical evidence of recurrent prostate cancer after definitive therapy[14,15]
- Biochemical recurrence (BCR) was defined as PSA >0.2 ng/mL more than 6 weeks after prostatectomy or an increase in serum PSA of at least 2 ng/mL above nadir after definitive radiotherapy[14,15]
- All patients received a single gallium Ga 68 gozetotide PSMA PET/CT or PSMA PET/MRI from mid-thigh to skull base; 210 had composite standard information collected in a PET-positive region (evaluable patients) consisting of at least 1 of the following: Histopathology, imaging (bone scintigraphy, CT, or MRI) acquired at baseline or within 12 months after gallium Ga 68 gozetotide PET, or serial serum PSA

After 3 members of a pool of 9 independent central readers evaluated each PSMA PET/CT and PSMA PET/MRI scan[15]:

91% of evaluable patients were found to be true positive in 1 or more regions against the composite reference standard (95% CI, 88%-95%).[a]

Higher PSA = greater chance of detecting PSMA+ lesions

The likelihood of identifying a gallium Ga 68 gozetotide PET–positive lesion in this study generally increased with higher serum PSA level.

[a] Among the pool of 9 readers used in the study, the proportion of patients who were true positive in 1 or more regions ranged from 82% to 97%.

For patients with suspected recurrence, consider a PSMA PET/CT scan if you see[b]:

- PSA >0.2 ng/mL more than 6 weeks after prostatectomy, or
- Increase in serum PSA of at least 2 ng/mL above nadir after definitive radiotherapy

[b] Based on inclusion criteria for the PSMA-BCR study. Institutional guidelines may vary.

PSMA PET imaging* can help guide management of prostate cancer across multiple settings[11-16]

Consider patients in your practice who could be candidates for a PSMA PET/CT scan and timing

For selection of patients who are indicated for PSMA-directed therapy as described in the prescribing information of the therapeutic products[15]

For patients with suspected metastasis who are candidates for initial definitive therapy[15,a]:

- Serum PSA of at least 10 ng/mL
- Tumor stage cT2b or greater
- Gleason score >6

For patients with suspected biochemical recurrence[15,b]:

- PSA >0.2 ng/mL more than 6 weeks after prostatectomy **or**
- Increase in serum PSA of at least 2 ng/mL above nadir after definitive radiotherapy

Referring your patients for a PSMA PET/CT scan starts with 1 simple step

Find the closest LOCAMETZ® (kit for the preparation of gallium Ga 68 gozetotide injection) scanning center to you and your patients as well as full contact information at **LOCAMETZ-hcp.com**.

*PSMA imaging includes PSMA PET/CT or PSMA PET/MRI.
[a] Based on inclusion criteria for the PSMA-PreRP study. Institutional guidelines may vary.
[b] Based on inclusion criteria for the PSMA-BCR study. Institutional guidelines may vary.

IMPORTANT SAFETY INFORMATION

Risk for Misinterpretation

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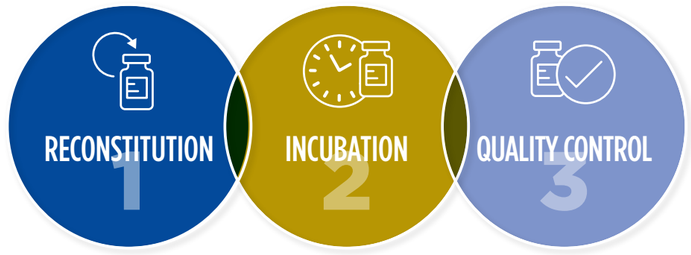
LOCAMETZ is available as a kit for the preparation of gallium Ga 68 gozetotide solution for injection[15]

Handling LOCAMETZ requires appropriate safety measures for minimizing radiation exposure[15,17]

- LOCAMETZ should be administered only under the control of trained/licensed HCPs
- Use waterproof gloves
- Use effective radiation shielding
- Minimize handling time[17]
- Any unused product or waste material should be disposed of in accordance with local and federal laws

LOCAMETZ can be prepared and labeled at the hospital radiopharmacy and used onsite or delivered to the hospital ready to inject

Radiolabeling of LOCAMETZ is accomplished in a 3-step process[15]



Videos for reconstituting and radiolabeling LOCAMETZ are available online

Find videos for using the Eckert & Ziegler GalliaPharm® and IRE ELiT Galli Eo™ generators at LOCAMETZ-hcp.com/psma-pet-ct/dosing-and-administration#resources

HCPs, health care providers.

Dosing and administration for LOCAMETZ® (kit for the preparation of gallium Ga 68 gozetotide injection)

Process for preparing the patient, verifying the dose, and proper disposal[15]

The recommended amount of radioactivity to be administered for PET is 111 MBq (3 mCi) up to a maximum of 259 MBq (7 mCi). Administered as a slow intravenous injection.

Prior to administration

Prior to use, **visually inspect the prepared gallium Ga 68 gozetotide solution for injection** behind a lead-glass shield for radioprotection purposes. Use only solutions that are clear, colorless, and free from particulate matter

After radiolabeling, **gallium Ga 68 gozetotide injection may be diluted with sterile water for injection**, USP, or 0.9% sodium chloride injection, USP up to a final volume of 10 mL

Advise patients to **be well hydrated prior to administration** and to void immediately prior to and frequently after image acquisition to reduce radiation exposure

Administration

Using a single-dose syringe fitted with a sterile needle (size 21G-23G) and protective shielding, aseptically withdraw the prepared gallium Ga 68 gozetotide solution

Verify the total radioactivity in the syringe with a dose calibrator immediately before administration to the patient. The dose calibrator must be calibrated with NIST traceable standards

If clinically necessary, **a diuretic expected to act within the uptake time period may be administered** at the time of radiotracer injection to potentially decrease artifact from radiotracer accumulation in the urinary bladder and ureters

NIST, National Institute of Standards and Technology; USP, US Pharmacopeia.

Please see additional Important Safety Information throughout and on page 13 and full Prescribing Information.

After administration

After administration, **verify the total radioactivity in the syringe** with a dose calibrator

Administer an intravenous flush of sterile 0.9% sodium chloride injection, USP, to ensure full delivery of the dose

Dispose of any unused gallium Ga 68 gozetotide solution **in a safe manner in compliance with applicable regulations**

After radiolabeling, gallium Ga 68 gozetotide solution for injection must be used within 6 hours[15]

IMPORTANT SAFETY INFORMATION (continued)

Risk for Misinterpretation (continued)

The performance of LOCAMETZ seems to be affected by serum PSA levels and by site of disease for imaging of biochemically recurrent prostate cancer, and by Gleason score for imaging of metastatic pelvic lymph nodes prior to initial definitive therapy.

LOCAMETZ allows visualization of PSMA+ metastases—regardless of location—in accordance with established guidelines[15,18]

How to acquire images using LOCAMETZ® (kit for the preparation of gallium Ga 68 gozetotide injection)[15]

1. PREPARE AND ADMINISTER LOCAMETZ

Follow the recommended dosing and administration instructions in the full Prescribing Information

2. ALLOW FOR REQUIRED UPTAKE TIME

Acquire PET images 50 to 100 minutes after the intravenous administration of LOCAMETZ

3. ACQUIRE THE IMAGE

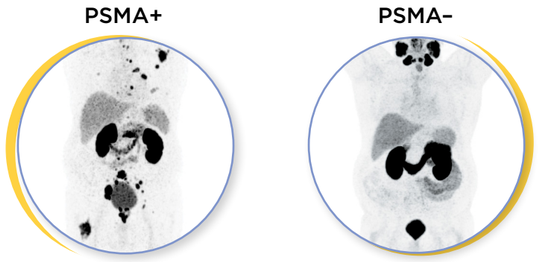
Scan the whole body, starting at mid-thigh and proceeding to skull base or skull vertex

4. OPTIMIZE AS NEEDED

Adapt imaging technique according to the equipment used and patient characteristics

Recommendations for interpreting images made using LOCAMETZ follow current national and international guidelines[15,18]

- LOCAMETZ binds to PSMA. Based on the intensity of the signals, PSMA PET images obtained with gallium Ga 68 gozetotide indicate the presence of PSMA protein in tissue[15]
- Descriptions of location, extent, and intensity of PSMA ligand uptake are addressed in the most current SNMMI and EANM guidelines on prostate cancer imaging with gallium Ga 68 gozetotide[18]
- Image interpretation errors can occur with LOCAMETZ PET. Read more on the **Risk for Misinterpretation** warning within the Important Safety Information on page 13.



EANM, European Association of Nuclear Medicine; PSMA–, PSMA negative; SNMMI, Society of Nuclear Medicine and Molecular Imaging.

Please see additional Important Safety Information throughout and on page 13 and full Prescribing Information.

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LOCAMETZ safety profile[15]

The safety of gallium Ga 68 gozetotide has been established in 3 prospective studies in patients with prostate cancer

Adverse reactions (≥0.5%) in patients with metastatic prostate cancer who received gallium Ga 68 gozetotide injection in VISION

Adverse reactions	Gallium Ga 68 gozetotide injection (N = 1003) n (%)
General disorders	
Fatigue	**12** (1.2)
Gastrointestinal disorders	
Nausea	**8** (0.8)
Constipation	**5** (0.5)
Vomiting	**5** (0.5)

- In the PSMA-PreRP and PSMA-BCR studies using another formulation of gallium Ga 68 gozetotide, 960 patients received 1 dose of gallium Ga 68 gozetotide intravenously with the amount (mean ± SD) of radioactivity 188.7 ± 40.7 MBq (5.1 ± 1.1 mCi). The most commonly reported adverse reactions were nausea, diarrhea, and dizziness, occurring at a rate of <1%
- In the VISION study, 1003 patients with progressive metastatic castration-resistant prostate cancer received one dose of gallium Ga 68 gozetotide intravenously with the amount of radioactivity 167.1 ± 23.1 MBq (4.52 ± 0.62 mCi). Adverse reactions occurring at ≥0.5% are presented in the table above
- Adverse reactions occurring at a rate of <0.5% in the VISION study were diarrhea, dry mouth, injection site reactions, including injection site hematoma and injection site warmth, and chills

IMPORTANT SAFETY INFORMATION (continued)

Radiation Risk

Gallium Ga 68 gozetotide contributes to a patient's long-term cumulative radiation exposure, which is associated with an increased risk of cancer. Ensure safe handling to minimize radiation exposure to the patient and health care workers. Advise patients to be well hydrated prior to gallium Ga 68 gozetotide administration and to void immediately prior to and frequently during the first hours after image acquisition to reduce radiation exposure.

Resources are available to help with access and reimbursement for LOCAMETZ

Novartis Patient Support™

Connect patients with support services for their experience with PSMA PET imaging using LOCAMETZ® (kit for the preparation of gallium Ga 68 gozetotide injection).

What is Novartis Patient Support?

Novartis Patient Support is a comprehensive program that helps your patients start and stay on treatment.

After enrollment, Novartis Patient Support can assist with:

- ☑ Insurance support
- ☑ Coding & billing support

SUPPORT BEGINS WITH PATIENT ENROLLMENT

Visit our website to download, complete, and submit the enrollment form to get started with Novartis Patient Support.

References: 1. Davis MI, Bennett MJ, Thomas LM, Bjorkman P. Crystal structure of prostate-specific membrane antigen, a tumor marker and peptidase. *Proc Natl Acad Sci U S A.* 2005;102(17):5981-5986. **2.** Liu H, Rajasekaran, AK, Moy P, et al. Constitutive and antibody-induced internalization of prostate-specific membrane antigen. *Cancer Res.* 1998;58(18): 4055-4060. **3.** Rajasaekaran SA, Anilkumar G, Oshima E, et al. A novel cytoplasmic tail MXXXL motif mediates the internalization of prostate-specific membrane antigen. *Mol Biol Cell.* 2003;14(12):4835-4845. **4.** Wright GL Jr, Grob BM, Haley C, et al. Upregulation of prostate-specific membrane antigen after androgen-deprivation therapy. *Urology.* 1996;48(2):326-334. **5.** Hupe MC, Philippi C, Roth D, et al. Expression of prostate-specific membrane antigen (PSMA) on biopsies is an independent risk stratifier of prostate cancer patients at time of initial diagnosis. *Front Oncol.* 2018;8:623. **6.** Hope TA, Aggarwal R, Chee B, et al. Impact of ^{68}Ga-PSMA-11 PET on management in patients with biochemically recurrent prostate cancer. *J Nucl Med.* 2017;58(12):1956-1961. **7.** Minner S, Wittmer C, Graefen M, et al. High level PSMA expression is associated with early PSA recurrence in surgically treated prostate cancer. *Prostate.* 2011;71(3):281-288. **8.** Pomykala KL, Czernin J, Grogan TR, Armstrong W, Williams J, Calais J. Total-body ^{68}Ga-PSMA-11 PET/CT for bone metastasis detection in prostate cancer patients: potential impact on bone scan guidelines. *J Nucl Med.* 2020;61(3):405-411. **9.** Tsourlakis MC, Klein F, Kluth M, et al. PSMA expression is highly homogenous in primary prostate cancer. *Appl Immunohistochem Mol Morphol.* 2015;23(6):449-455. **10.** Troyer JK, Beckett ML, Wright GL Jr. Detection and characterization of the prostate-specific membrane antigen (PSMA) in tissue extracts and body fluids. *Int J Cancer.* 1995;62(5):552-558. **11.** Fendler WP, Weber M, Iravani A, et al. Prostate-specific membrane antigen ligand positron emission tomography in men with nonmetastatic castration-resistant prostate cancer. *Clin Cancer Res.* 2019;25(24):7448-7454. **12.** Hofman MS, Lawrentschuk N, Francis RJ, et al. Prostate-specific membrane antigen PET-CT in patients with high-risk prostate cancer before curative-intent surgery or radiotherapy (proPSMA): a prospective, randomised, multicentre study. *Lancet.* 2020;395(10231):1208-1216. **13.** Sonni I, Eiber M, Fendler WP, et al. Impact of ^{68}Ga-PSMA-11 PET/CT on staging and management of prostate cancer patients in various clinical settings: a prospective single-center study. *J Nucl Med.* 2020;61(8):1153-1160. **14.** Fendler WP, Calais J, Eiber M, et al. Assessment of ^{68}Ga-PSMA-11 PET accuracy in localizing recurrent prostate cancer: a prospective single-arm clinical trial. *JAMA Oncol.* 2019;5(6):856-863. **15.** Locametz. Prescribing information. Novartis Pharmaceuticals Corp. **16.** Sartor O, de Bono J, Chi KN, et al; VISION Investigators. Lutetium-177–PSMA- 617 for metastatic castration-resistant prostate cancer. *N Engl J Med.* 2021;385(12):1091-1103. doi:10.1056/NEJMoa2107322 **17.** ALARA - as low as reasonably achievable. Centers for Disease Control and Prevention. https://www.cdc.gov/nceh/radiation/alara.html. **18.** Fendler WP, Eber M, Beheshti M, et al. ^{68}Ga-PSMA PET/CT: Joint EANM and SNMMI procedure guideline for prostate cancer imaging: version 1.0. *Eur J Nucl Med Mol Imaging.* 2017;44(6):1014-1024. doi:10.1007/s00259-017-3670-z

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The performance of LOCAMETZ seems to be affected by serum PSA levels and by site of disease for imaging of biochemically recurrent prostate cancer, and by Gleason score for imaging of metastatic pelvic lymph nodes prior to initial definitive therapy.

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Adverse Reactions

Adverse reactions ≥0.5% in the VISION study were fatigue (1.2%), nausea (0.8%), constipation (0.5%), and vomiting (0.5%). Adverse reactions occurring at a rate of <0.5% were diarrhea, dry mouth, injection site reactions, and chills.

Please see full Prescribing Information.

LOCAMETZ®

Kit for the preparation of gallium Ga 68 gozetotide

INJECTION FOR INTRAVENOUS USE

Approved for PSMA/PET imaging in prostate cancer

For more information on LOCAMETZ® (kit for the preparation of gallium Ga 68 gozetotide injection) and to find a scanning center near you or your patient, please visit LOCAMETZ-hcp.com.

How to Order LOCAMETZ

LOCAMETZ after radiolabeling with gallium-68 is distributed through a network of radiopharmacies.

To order radiolabeled LOCAMETZ delivered ready to inject, please contact your local radiopharmacy. Or refer your patient for a PSMA PET scan at your **local scanning center** today.

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