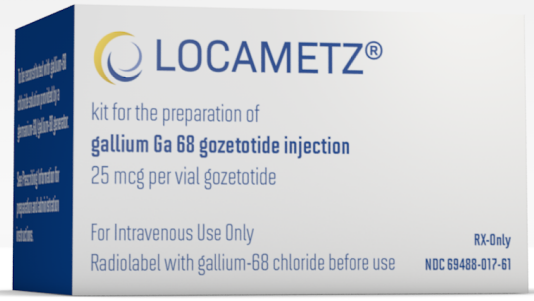
LOCAMETZ®
Kit for the preparation of gallium Ga 68 gozetotide
INJECTION FOR INTRAVENOUS USE

Dosing and administration for LOCAMETZ® (kit for the preparation of gallium Ga 68 gozetotide injection)[1]



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 4 and full Prescribing Information.

Process for preparing the patient, verifying the dose, and proper disposal[1]

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.

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.

Please see additional Important Safety Information throughout and on page 4 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[1]

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.

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.

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Please see full Prescribing Information.

Reference: 1. Locametz. Prescribing information. Novartis Pharmaceuticals Corp.

To learn more about LOCAMETZ, please visit LOCAMETZ-hcp.com.

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