



Not shown to scale

Product specification guide for:

## NETSPOT® (kit for the preparation of gallium Ga 68 dotatate injection)

Marketed and manufactured by Advanced Accelerator Applications USA, Inc.

● <b>Brand Name</b>	NETSPOT
● <b>Established/Generic Name</b>	Kit for the preparation of gallium Ga 68 dotatate injection
● <b>Product Formulation</b>	Single-dose kit for injection containing: • Vial 1 (light blue cap) (reaction vial with lyophilized powder) containing 40 µg of dotatate (3) • Vial 2 (yellow cap) (reaction buffer vial) containing 1 mL of reaction buffer solution
● <b>Product National Drug Code</b>	69488-001-40
● <b>Product Price (WAC)</b>	\$3000.00 per single dose
● <b>Product HCPCS Code<sup>1</sup></b>	A9587
● <b>Product Nomenclature</b>	A radioactive diagnostic agent for use with positron emission tomography (PET)
● <b>Dosing and Administration</b>	After reconstitution and radiolabeling, recommended dose in adult and pediatric patients is 2 MBq/kg of body weight (0.054 mCi/kg) up to 200 MBq (5.4 mCi) administered as intravenous bolus injection

HCPCS, Healthcare Common Procedure Coding System; WAC, wholesale acquisition cost.

**Starting January 1, 2022, customers will purchase NETSPOT through select, contracted commercial radiopharmacies. For additional information, please contact Advanced Accelerator Applications Customer Service at 1-844-DOSE-AAA. Customer Service is available from 9:00 AM to 8:00 PM ET, Monday through Friday.**

**DISCLAIMER: It is the provider’s responsibility to determine and submit accurate information on claims and comply with payer coverage, reimbursement, and claim submission rules. The existence of billing codes does not guarantee coverage and payment.**

### INDICATION<sup>2</sup>

NETSPOT®, kit for the preparation of gallium Ga 68 dotatate injection after radiolabeling with Ga 68, is a radioactive diagnostic agent indicated for use with positron emission tomography (PET) for localization of somatostatin receptor positive neuroendocrine tumors (NETs) in adult and pediatric patients.

### IMPORTANT SAFETY INFORMATION

#### WARNINGS AND PRECAUTIONS

##### Radiation Risk

- Radiopharmaceuticals should be used by or under the control of physicians who are qualified by specific training and experience in the safe use and handling of radionuclides

Please see additional Important Safety Information on next page and full [Prescribing Information](#).

**NETSPOT®**  
Kit for the preparation of gallium Ga 68 dotatate injection for intravenous use

# IMPORTANT SAFETY INFORMATION (continued)

## WARNINGS AND PRECAUTIONS (continued)

### Radiation Risk (continued)

- Ga 68 dotatate contributes to a patient's overall long-term cumulative radiation exposure. Long-term cumulative radiation exposure is associated with an increased risk of cancer
- Ensure safe handling and preparation reconstitution procedures to protect patients and health care workers from unintentional radiation exposure
- Instruct patients to drink enough water to ensure adequate hydration prior to the administration of Ga 68 dotatate. Patients should drink and void frequently during the first hours following administration to reduce radiation exposure
- Patients should avoid close contact with infants and pregnant women during the first 12 hours after the administration of Ga 68 dotatate

### Hypersensitivity Reactions

- Hypersensitivity reactions following the administration of somatostatin receptor imaging agents predominantly consisted of cutaneous reactions, such as rash and pruritus. Reactions reversed either spontaneously or with routine symptomatic management. Less frequently, hypersensitivity reactions included angioedema or cases with features of anaphylaxis

### Risk for Image Misinterpretation

- The uptake of Ga 68 dotatate reflects the level of somatostatin receptor density in NETs. However, uptake can also be seen in a variety of other tumor types (eg, those derived from neural crest tissue)
- Increased uptake might also be seen in sites of splenosis or other pathologic conditions (eg, thyroid disease or subacute inflammation) or might occur as a normal physiologic variant (eg, uncinata process of the pancreas)
- PET images with Ga 68 dotatate should be interpreted visually and the uptake may need to be confirmed by histopathology or other assessments
- A negative scan after the administration of Ga 68 dotatate in patients who do not have a history of NETs, including in patients suspected of having ectopic ACTH-secreting tumors, does not rule out the presence of NETs

## ADVERSE REACTIONS

- **Clinical Trial Experience:** The safety of Ga 68 dotatate was evaluated in 3 single-center studies and in a survey of the scientific literature. No serious adverse reactions were identified

## DRUG INTERACTIONS

- Nonradioactive somatostatin analogs competitively bind to the same somatostatin receptors as Ga 68 dotatate. Image patients with Ga 68 dotatate PET just prior to dosing with long-acting somatostatin analogs
- Short-acting somatostatin analogs can be used up to 24 hours before imaging with Ga 68 dotatate
- Corticosteroids can downregulate subtype 2 somatostatin receptors. Repeated administration of high doses of glucocorticoids prior to Ga 68 dotatate administration may result in false-negative imaging

## SPECIFIC POPULATIONS

### Pregnancy

- No studies exist with Ga 68 dotatate in pregnant women to inform any drug-associated risks; however, all radiopharmaceuticals, including Ga 68 dotatate, have the potential to cause fetal harm

### Lactation

- No information exists on the presence of Ga 68 dotatate in human milk, the effect on the breastfed infant, or the effect on milk production
- Advise a lactating woman to interrupt breastfeeding and pump and discard breast milk for 12 hours after Ga 68 dotatate administration to minimize radiation exposure to a breastfed infant

## OVERDOSAGE

- In the event of a radiation overdose, the absorbed dose to the patient should be reduced where possible by increasing the elimination of the radionuclide from the body by reinforced hydration and frequent bladder voiding. A diuretic might also be considered
- If possible, an estimate of the radioactive dose given to the patient should be performed

**To report SUSPECTED ADVERSE REACTIONS, contact Novartis Pharmaceuticals Corporation at 1-888-669-6682 or [www.report.novartis.com](http://www.report.novartis.com), or the FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch). Please see full [Prescribing Information](#).**

Distributed by Advanced Accelerator Applications USA, Inc, NJ 07041

**References:** 1. Centers for Medicare & Medicaid Services. HCPCS Quarterly Update. <https://www.cms.gov/Medicare/Coding/HCPCS-ReleaseCodeSets/HCPCS-Quarterly-Update>. Updated July 2021. Accessed August 11, 2021. 2. Netspot [prescribing information]. Millburn, NJ: Advanced Accelerator Applications; 2021.

Advanced Accelerator Applications USA, Inc  
57 East Willow Street, Millburn, NJ 07041

© 2022 Advanced Accelerator Applications. All Rights Reserved.  
173672 | 1/22

**NETSPOT®**

Kit for the preparation  
of gallium Ga 68 dotatate  
injection for intravenous use