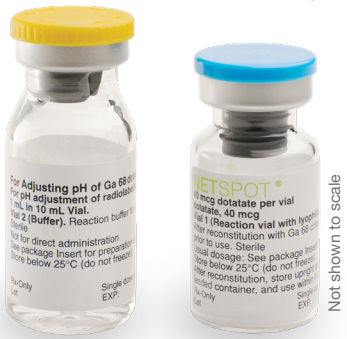
NETSPOT At A Glance



Product specification guide for:

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

Marketed and manufactured by Novartis Pharmaceuticals Corporation.

Brand Name	NETSPOT
Established/Generic Name	Kit for the preparation of gallium Ga 68 dotatate injection
Product Formulation	Single-dose kit for injection containing: • Vial 1 (light blue cap) (reaction vial with lyophilized powder) containing 40 mcg of dotatate (3) • Vial 2 (yellow cap) (reaction buffer vial) containing 1 mL of reaction buffer solution
Product National Drug Code	69488-001-40
Product Price (WAC)	$3120.00 per single dose
Product HCPCS Code[1]	A9587
Product Nomenclature	A radioactive diagnostic agent for use with positron emission tomography (PET)
Dosing and Administration	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 Novartis Pharmaceuticals Corporation Customer Service at 1-844-367-3222. Customer Service is available from 8:00 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[2]

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, uncinate 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, or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see full Prescribing Information.

Distributed by: Novartis Pharmaceuticals Corporation, East Hanover, New Jersey 07936

References: 1. HCPCS Quarterly Update. Updated May 24, 2023. Accessed June 16, 2023. https://www.cms.gov/medicare/coding/hcpcsreleasecodesets/hcpcs-quarterly-update **2.** Netspot. Prescribing Information. Advanced Accelerator Applications.

NETSPOT®

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

NOVARTIS

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