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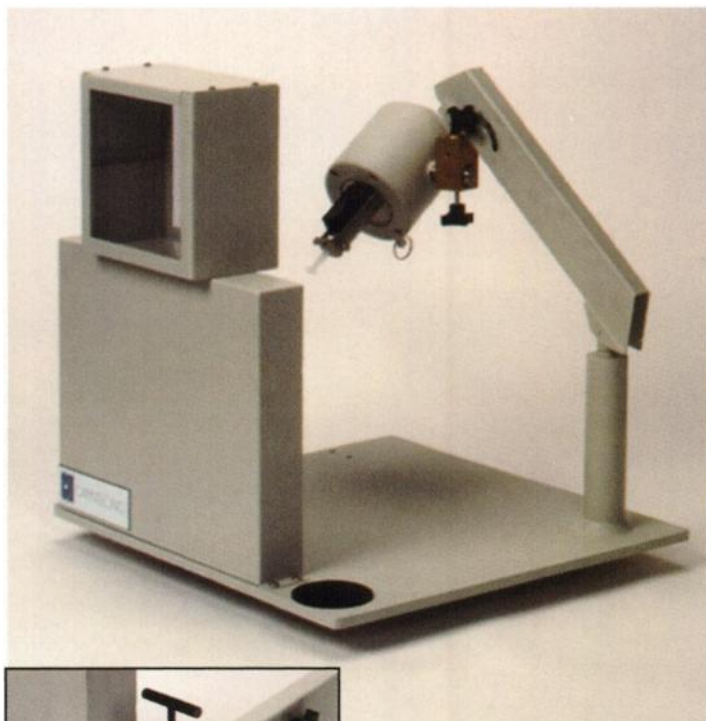
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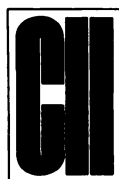
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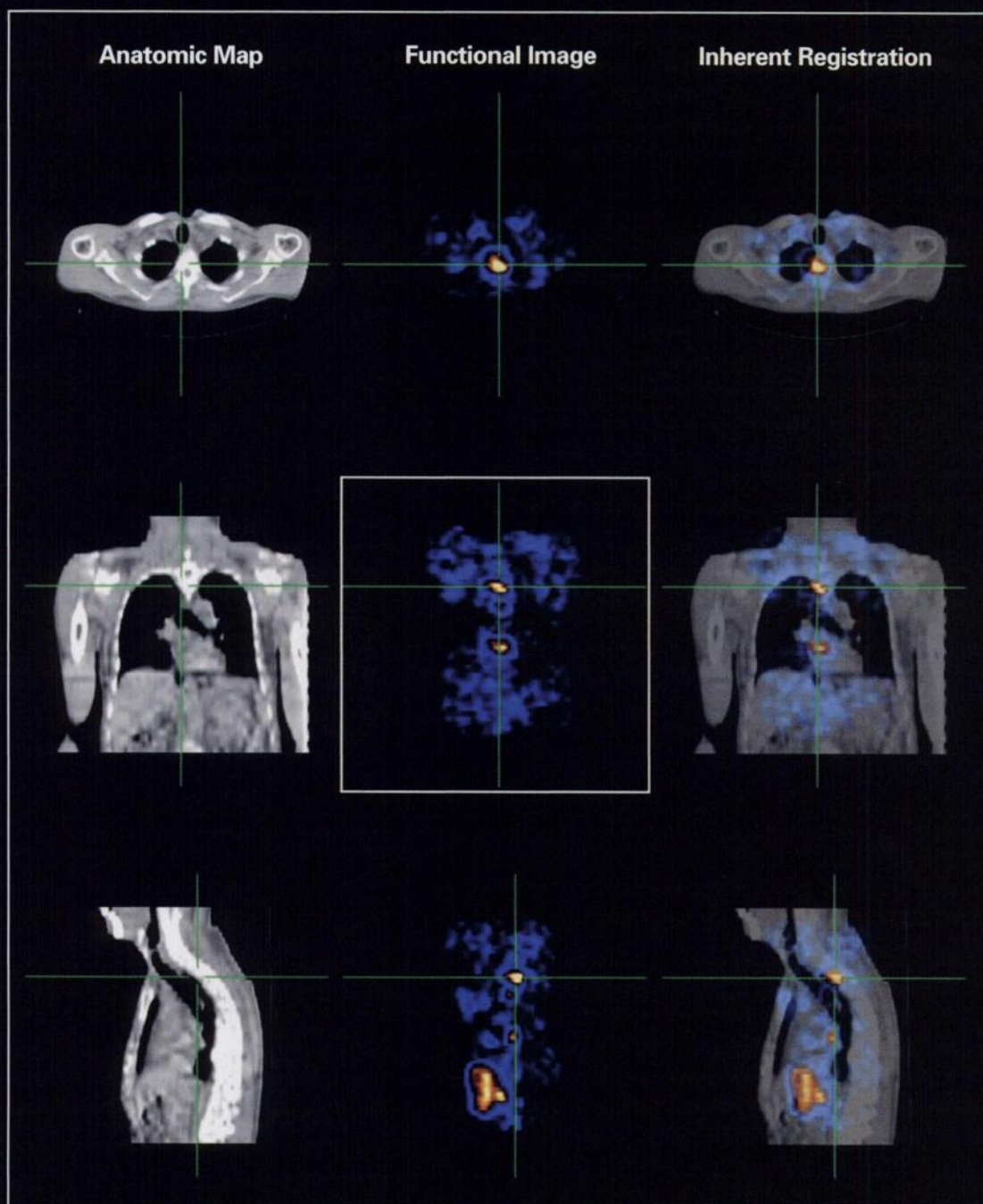
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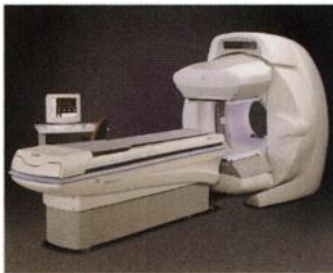
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 - stage the patient
 - determine diagnostic work-up
 - avoid unnecessary procedures
 - select optimal treatment
 - assess surgical candidates
 - evaluate response to treatment
- Transient adverse effects including dizziness, fever, flush, headache, hypotension, changes in liver enzymes, joint pain, nausea, sweating, and weakness were observed in less than 1% of 538 patients during clinical trials.
- Please see the prescribing information for special considerations regarding patients receiving total parenteral nutrition or concurrent octreotide acetate therapy and patients with insulinoma or impaired renal function.

*The accepted standard
for GEP* tumors*

*An emerging choice for
small cell lung cancer*

*Gastroentero-pancreatic neuroendocrine tumors



OCTREOSCAN®

Kit for the Preparation of Indium In-111 Pentetreotide

Please see adjacent page for brief summary of prescribing information.

OCTREOSCAN[®]

Kit for the Preparation of Indium In-111 Pentetreotide

BRIEF SUMMARY OF PRESCRIBING INFORMATION

DESCRIPTION

OctreoScan[®] is a kit for the preparation of indium In-111 pentetreotide, a diagnostic radio-pharmaceutical. It is a kit consisting of two components:

- 1) A 10-mL OctreoScan Reaction Vial which contains a lyophilized mixture of 10 µg pentetreotide.
- 2) A 10-mL vial of Indium In-111 Chloride Sterile Solution.

Indium In-111 pentetreotide is prepared by combining the two kit components.



INDICATIONS AND USAGE

Indium In-111 pentetreotide is an agent for the scintigraphic localization of primary and metastatic neuroendocrine tumors bearing somatostatin receptors.

CONTRAINDICATIONS

None known.

WARNINGS

DO NOT ADMINISTER IN TOTAL PARENTERAL NUTRITION (TPN) ADMIXTURES OR INJECT INTO TPN INTRAVENOUS ADMINISTRATION LINES. IN THESE SOLUTIONS, A COMPLEX GLYCOSYL OCTREOTIDE CONJUGATE MAY FORM.

The sensitivity of scintigraphy with indium In-111 pentetreotide may be reduced in patients concurrently receiving therapeutic doses of octreotide acetate. Consideration should be given to temporarily suspending octreotide acetate therapy before the administration of indium In-111 pentetreotide and to monitoring the patient for any signs of withdrawal.

PRECAUTIONS

General

1. Therapy with octreotide acetate can produce severe hypoglycemia in patients with insulinomas. Since pentetreotide is an analog of octreotide, an intravenous line is recommended in any patient suspected of having an insulinoma. An intravenous solution containing glucose should be administered just before and during administration of indium In-111 pentetreotide.
2. The contents of the two vials supplied with the kit are intended only for use in the preparation of indium In-111 pentetreotide and are NOT to be administered separately to the patient.
3. Since indium In-111 pentetreotide is eliminated primarily by renal excretion, use in patients with impaired renal function should be carefully considered.
4. To help reduce the radiation dose to the thyroid, kidneys, bladder, and other target organs, patients should be well hydrated before the administration of indium In-111 pentetreotide. They should increase fluid intake and void frequently for one day after administration of this drug. In addition, it is recommended that patients be given a mild laxative (e.g., bisacodyl or lactulose) before and after administration of indium In-111 pentetreotide (see Dosage and Administration section).
5. Indium In-111 pentetreotide should be tested for labeling yield of radioactivity prior to administration. The product must be used within six hours of preparation.
6. Components of the kit are sterile and nonpyrogenic. To maintain sterility, it is essential that directions are followed carefully. Aseptic technique must be used during the preparation and administration of indium In-111 pentetreotide.
7. Octreotide acetate and the natural somatostatin hormone may be associated with cholelithiasis, presumably by altering fat absorption and possibly by decreasing motility of the gallbladder. A single dose of indium In-111 pentetreotide is not expected to cause cholelithiasis.
8. As with any other radioactive material, appropriate shielding should be used to avoid unnecessary radiation exposure to the patient, occupational workers, and other persons.
9. Radiopharmaceuticals should be used only by physicians who are qualified by specific training in the safe use and handling of radionuclides.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Studies have not been performed with indium In-111 pentetreotide to evaluate carcinogenic potential or effects on fertility. Pentetreotide was evaluated for mutagenic potential in an in vitro mouse lymphoma forward mutation assay and an in vivo mouse micronucleus assay; evidence of mutagenicity was not found.

Pregnancy Category C

Animal reproduction studies have not been conducted with indium In-111 pentetreotide. It is not known whether indium In-111 pentetreotide can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Therefore, indium In-111 pentetreotide should not be administered to a pregnant woman unless the potential benefit justifies the potential risk to the fetus.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when indium In-111 pentetreotide is administered to a nursing woman.

Pediatric Use

Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

The following adverse effects were observed in clinical trials at a frequency of less than 1% of 538 patients: dizziness, fever, flush, headache, hypotension, changes in liver enzymes, joint pain, nausea, sweating, and weakness. These adverse effects were transient. Also in clinical trials, there was one reported case of bradycardia and one case of decreased hematocrit and hemoglobin.

Pentetreotide is derived from octreotide which is used as a therapeutic agent to control symptoms from certain tumors. The usual dose for indium In-111 pentetreotide is approximately 5 to 20 times less than for octreotide and is subtherapeutic. The following adverse reactions have been associated with octreotide in 3% to 10% of patients: nausea, injection site pain, diarrhea, abdominal pain/discomfort, loose stools, and vomiting. Hypertension and hyper- and hypoglycemia have also been reported with the use of octreotide.

DOSAGE AND ADMINISTRATION

Before administration, a patient should be well hydrated. After administration, the patient must be encouraged to drink fluids liberally. Elimination of extra fluid intake will help reduce the radiation dose by flushing out unbound, labeled pentetreotide by glomerular filtration. It is also recommended that a mild laxative (e.g., bisacodyl or lactulose) be given to the patient starting the evening before the radioactive drug is administered, and continuing

for 48 hours. Ample fluid uptake is necessary during this period as a support both to renal elimination and the bowel-cleansing process. In a patient with an insulinoma, bowel-cleansing should be undertaken only after consultation with an endocrinologist.

The recommended intravenous dose for planar imaging is 111 MBq (3.0 mCi) of indium In-111 pentetreotide prepared from an OctreoScan kit. The recommended intravenous dose for SPECT imaging is 222 MBq (6.0 mCi) of indium In-111 pentetreotide.

The dose should be confirmed by a suitably calibrated radioactivity ionization chamber immediately before administration.

As with all intravenously administered products, OctreoScan should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Preparations containing particulate matter or discoloration should not be administered. They should be disposed of in a safe manner, in compliance with applicable regulations.

Aseptic techniques and effective shielding should be employed in withdrawing doses for administration to patients. Waterproof gloves should be worn during the administration procedure.

Do not administer OctreoScan in TPN solutions or through the same intravenous line.

Radiation Dosimetry

The estimated radiation doses¹ to the average adult (70 kg) from intravenous administration of 111 MBq (3 mCi) and 222 MBq (6 mCi) are presented below. These estimates were calculated by Oak Ridge Associated Universities using the data published by Krenning, et al.²

Estimated Absorbed Radiation Doses after Intravenous Administration of Indium In-111 Pentetreotide³ to a 70 kg patient

	PLANAR		SPECT	
Kidneys	54.16	5.42	108.32	10.83
Liver	12.15	1.22	24.31	2.43
Spleen	73.86	7.39	147.73	14.77
Uterus	6.34	0.63	12.67	1.27
Ovaries	4.89	0.49	9.79	0.98
Testes	2.90	0.29	5.80	0.58
Red Marrow	3.46	0.35	6.91	0.69
Urinary Bladder Wall	30.42	3.04	60.48	6.05
GI Tract				
Stomach Wall	5.67	0.57	11.34	1.13
Small Intestine	4.78	0.48	9.56	0.96
Upper Large Intestine	5.80	0.58	11.59	1.16
Lower Large Intestine	7.73	0.77	15.46	1.55
Adrenals	7.55	0.76	15.11	1.51
Thyroid	7.43	0.74	14.86	1.49
Effective Dose ⁴ Equivalent	13.03	1.30	26.06	2.61

1. Values listed include a correction for a maximum of 0.1% indium In-114m radiocontaminant at calibration.

2. E.P. Krenning, W.H. Bakker, P.M. Kooij, W.A.P. Breeman, H.Y. Oei, M. de Jong, J.C. Reubi, T.J. Visser, C. Bruns, D.J. Kwekkeboom, A.E.M. Reij, P.M. van Hagen, J.W. Koper, and S.W.J. Lamberts, "Somatostatin Receptor Scintigraphy with Indium-111-DTPA-D-Phe-1-Octreotide in Man: Metabolism, Dosimetry and Comparison with Iodine-123-Tyr-3-Octreotide," *The Journal of Nuclear Medicine*, Vol. 33, No. 5, May 1992, pp. 652-658.

3. Assumes 4.8 hour voiding interval and International Commission on Radiological Protection (ICRP) 30 model for the gastrointestinal tract calculations.

4. Estimated according to ICRP Publication 53.

HOW SUPPLIED

The OctreoScan kit, NDC 0019-9050-40, is supplied with the following components:

1. A 10-mL OctreoScan Reaction Vial which contains a lyophilized mixture of:
 - (i) 10 µg pentetreotide [N-(diethylenetriamine-N,N',N''-tetraacetic acid-N'-acetyl)-D-phenylalanyl-L-hemicyclic-L-phenylalanyl-D-tryptophyl-L-tyrosyl-L-threonyl-L-hemicyclic-L-threoninol cyclic (2-7) disulfide], (also known as octreotide DTPA),
 - (ii) 2.0 mg gentisic acid [2,5-dihydroxybenzoic acid],
 - (iii) 4.9 mg trisodium citrate, anhydrous,
 - (iv) 0.37 mg citric acid, anhydrous, and
 - (v) 10.0 mg inositol.

Before lyophilization, sodium hydroxide or hydrochloric acid may have been added for pH adjustment. The vial contents are sterile and nonpyrogenic. No bacteriostatic preservative is present.

2. A 10-mL vial of Indium In-111 Chloride Sterile Solution, which contains 1.1 mL of 111 MBq/mL (3.0 mCi/mL) indium In-111 chloride in 0.02 N HCl at time of calibration. The vial also contains ferric chloride at a concentration of 3.5 µg/mL (ferric ion, 1.2 µg/mL). The vial contents are sterile and nonpyrogenic. No bacteriostatic preservative is present.

In addition, the kit also contains the following items: (1) a 25 G x 5/8" needle (B-D, Monoject) used to transfer Indium In-111 Chloride Sterile Solution to the OctreoScan Reaction Vial, (2) a pressure sensitive label, and (3) a package insert.

MALLINCKRODT

Mallinckrodt Inc.,
Mallinckrodt Nuclear Medicine Division
P.O. Box 5840
St. Louis, MO 63134

1. Termanini B, Gibril F, Reynolds JC, et al. Value of Somatostatin Receptor Scintigraphy: A Prospective Study in Gastrinoma of its Effect on Clinical Management. *Gastroenterology* 1997;112:335-337.

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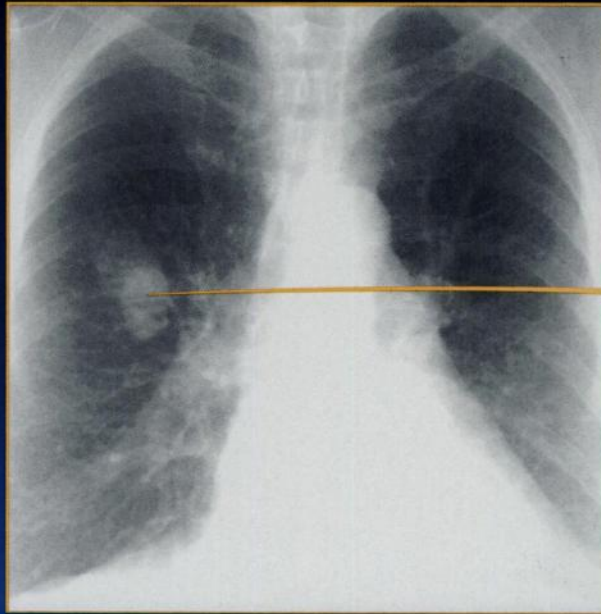
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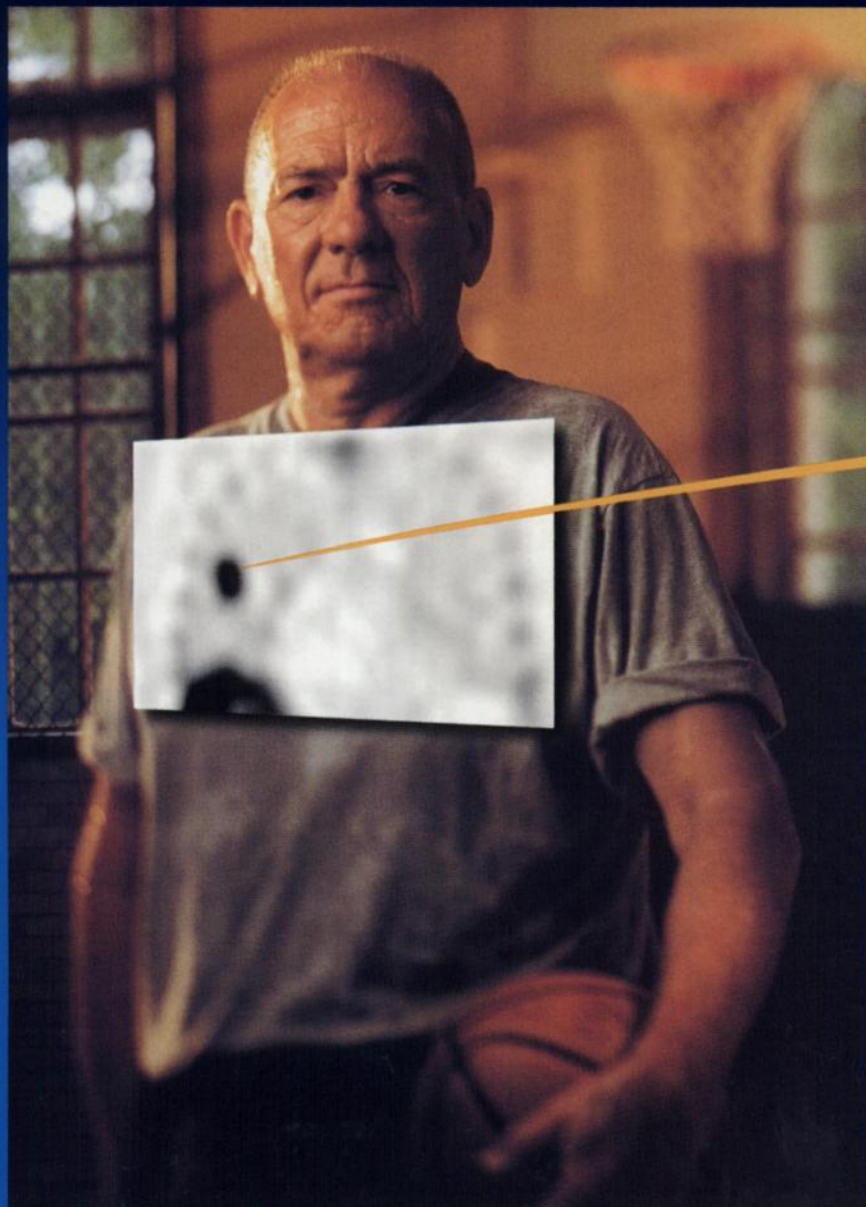


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INTRODUCING
NeoTect™

Kit for the Preparation of Technetium Tc 99m Depreotide Injection

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BOUND
TO
SEE
MORE

Indicated to identify somatostatin receptor-bearing pulmonary masses in patients who are known to have or are highly suspect for malignancy and have pulmonary lesions on CT and /or chest x-ray.¹

Noninvasively Characterizes Pulmonary Masses

Normal
SPECT image

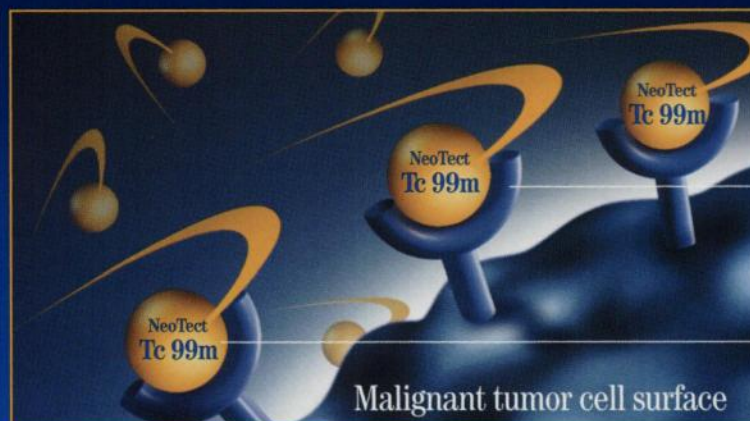


Positive SPECT
image, malignancy
confirmed by histology
(adenocarcinoma)



- **NeoTect™, a unique small synthetic peptide radiopharmaceutical, characterizes pulmonary masses as being rich in somatostatin receptors (SSTRs)^{1,2}**
 - Many malignant pulmonary masses and some inflammatory processes overexpress SSTRs¹

Unique mechanism of action



Somatostatin
receptor

NeoTect
radiolabeled peptide

- **NeoTect, which is radiolabeled with technetium Tc 99m, produces high contrast resolution single photon emission computed tomography (SPECT) images within 2 to 4 hours,¹ with little generalized pulmonary uptake²**
- **Achieves high specificity and sensitivity values, reliable readings^{1,2}**
- **Offers an excellent safety profile¹ without the serious complications (eg, pneumothorax³) associated with invasive procedures**
 - Of 647 patients evaluated, one or more adverse events occurred in only 4.5% of all enrolled patients. The most commonly reported adverse events were headache (1.0%), dizziness (0.8%), nausea (0.6%), and flushing (0.5%).¹
 - NeoTect, as other small peptides, may induce hypersensitivity reactions or anaphylactic reactions. Adequate treatment provisions, including epinephrine, should be available for immediate use.¹

The clinical benefit of NeoTect as a population-based screening tool has not been studied. NeoTect is not an alternative to CT or biopsy.¹

Please see brief summary of prescribing information on following page.

EXPANDING YOUR VISION

NEW NeoTect™

Kit for the Preparation of Technetium Tc 99m Depreotide Injection

Brief Summary of Prescribing Information

DESCRIPTION

NeoTect™ (Kit for the Preparation of Technetium Tc 99m Depreotide Injection) is intended for use in the preparation of Technetium Tc 99m Depreotide, a diagnostic radiopharmaceutical to be used by intravenous injection. Each vial contains a sterile, non-pyrogenic lyophilized mixture of 50 µg of Depreotide, 5 mg of sodium glucoheptonate dihydrate, 50 µg of stannous chloride dihydrate (with a minimum stannous tin content of 15 µg), 100 µg edetate disodium dihydrate, and sufficient sodium hydroxide or hydrochloric acid for adjustment to pH 7.4 prior to lyophilization. The lyophilized powder is sealed under a nitrogen atmosphere with a rubber closure. The product contains no antimicrobial preservative.

When sterile, non-pyrogenic Sodium Pertechnetate Tc 99m Injection, in 0.9% Sodium Chloride Injection, U.S.P., is added to the vial, a Technetium Tc 99m complex of Depreotide is formed.

INDICATIONS AND USAGE

NeoTect™ is a scintigraphic imaging agent that identifies somatostatin receptor-bearing pulmonary masses in patients presenting with pulmonary lesions on computed tomography and/or chest x-ray who have known malignancy or who are highly suspect for malignancy.

CONTRAINDICATIONS

None known.

WARNINGS

None.

PRECAUTIONS

General

Therapy with somatostatin analogues can produce severe hypoglycemia in patients with insulinomas. Since Depreotide binds to somatostatin receptors, caution should be exercised when administering this drug to patients with insulinomas.

NeoTect™, as other small peptides, may induce hypersensitivity reactions or anaphylactic reactions. Adequate treatment provisions, including epinephrine, should be available for immediate use. In preliminary studies of 18 subjects, NeoTect™ did not produce increases in IgG or IgM production 3 weeks following injection. Other immune parameters such as eosinophils, other immunoglobulins, complement, lymphokines or cytokines were not studied.

Technetium Tc 99m Depreotide Injection, like other radioactive drugs, must be handled with care and appropriate safety measures should be used to minimize radiation exposure to clinical personnel. Care should also be taken to minimize radiation exposure to the patient consistent with proper patient management.

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, and whose experience and training have been approved by the appropriate governmental agency authorized to license the use of radionuclides.

Urinary excretion of radioactivity occurs primarily during the first 4 hours following injection. Studies have not been done to determine the amount of radioactivity that might be eliminated in the feces. (See Clinical Pharmacology Section.) Special precautions should be taken with incontinent patients to minimize the risk of radioactive contamination of clothing, bed linen, and the patient's environment.

Information For Patients

To minimize radiation absorbed dose to the bladder, adequate hydration should be encouraged to permit frequent voiding during the first few hours after injection of NeoTect™. This may be achieved by having patients drink at least an 8 oz. glass of water prior to drug administration. To help protect themselves and others in their environment, patients should take the following precautions for 12 hours after injection: whenever possible a toilet should be used and should be flushed several times after each use and patients should wash their hands thoroughly after each voiding or fecal elimination. If blood, urine or feces soil the clothing, the clothing should be washed separately.

Laboratory Tests

There was a low incidence (1% or less) of transient and clinically insignificant changes in alanine aminotransferase (ALT), white blood cell count, and eosinophil count following administration of Technetium Tc 99m Depreotide Injection.

Drug Interaction

Drug interactions were not noted in clinical studies in which Technetium Tc 99m Depreotide Injection was administered to patients receiving concomitant medication.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Studies have not been conducted to evaluate carcinogenic potential or effects on fertility. The results of the following genotoxicity studies with decayed Technetium Tc 99m Depreotide Injection or with depreotide were negative: *Salmonella/Escherichia coli* reverse mutation assay, *in vitro* mouse lymphoma assay with and without metabolic activation, and *in vivo* mouse micronucleus assay.

Pregnancy

Pregnancy Category C. Animal reproduction studies have not been conducted with decayed Technetium Tc 99m Depreotide Injection. It is not known whether Technetium Tc 99m Depreotide Injection can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Technetium Tc 99m Depreotide Injection should be given to a pregnant woman only if clearly needed. Studies in pregnant women have not been conducted.

Nursing Mothers

Studies have not been conducted with depreotide to determine its excretion in human milk. Technetium Tc 99m Pertechnetate is excreted in human milk. It is not known whether Technetium Tc 99m Depreotide Injection is excreted in human milk. Caution should be exercised when Technetium Tc 99m Depreotide Injection is administered to a nursing woman. Wherever possible, infant formula should be substituted for breast milk until the technetium has been eliminated.

Pediatric Use

Safety and effectiveness of Depreotide in pediatric patients below the age of 16 years have not been established.

ADVERSE REACTIONS

Adverse events were evaluated in clinical studies of 647 adults who received 15.0 to 20.0 mCi Technetium Tc 99m labeled to approximately 50 µg of depreotide. Of these adults, 58% were men

and 42% women. The mean age was 59.0 years (18-86 years).

Deaths did not occur during the clinical study period. After Technetium Tc 99m Depreotide Injection, serious adverse events were not reported.

At least one adverse event occurred in 29/647 (4.5 %) patients after Technetium Tc 99m Depreotide Injection. Headache was the most commonly reported adverse event (1% of patients). Table 8 lists adverse events reported in 0.5% or more of patients who received Technetium Tc 99m Depreotide Injection.

**TABLE 8
ADVERSE EVENTS REPORTED IN ≥ 0.5% OF PATIENTS FOLLOWING
NeoTect™ INJECTION IN CLINICAL TRIALS**

Number of Patients Exposed	647
Number of Patients with At Least One Adverse Event	29 (4.5%)
Nervous System	13 (2%)
Headache	7 (1.0%)
Dizziness	5 (0.8%)
Gastrointestinal System	7 (1.0%)
Nausea	4 (0.6%)
Vascular (extracardiac) Disorder	3 (0.5%)
Flushing	3 (0.5%)

Other adverse events which occurred in < 0.5% of patients following administration of NeoTect™ included: arthrosis, back pain, chest pain, diarrhea, fatigue, gait abnormality, glossitis, hemoptysis, hypoesthesia, infection, leg cramps, lymphocytosis, malaise, pharyngitis, somnolence, taste perversion.

DOSAGE AND ADMINISTRATION

For imaging, NeoTect™ is administered as a peripheral intravenous injection at a single dose of 15 to 20 mCi containing approximately 50 µg of Technetium Tc 99m radiolabeled Depreotide peptide.

Patients should drink at least an 8 oz. glass of water before drug administration.

The contents of Kit for the Preparation of Technetium Tc 99m Depreotide Injection are intended only for use in the preparation of Technetium Tc 99m Depreotide Injection and are not to be administered directly to the patient. Only one patient dose should be drawn from each reconstituted vial. (See Instructions for the Preparation Section.)

The potential need for dose adjustment has not been studied in patients with renal insufficiency, or in pediatric or geriatric patients, or in patients on therapeutic somatostatin analogues.

IMAGING

Planar and SPECT images of the chest should be obtained between 2-4 hours after NeoTect™ administration. SPECT images of the chest are required for optimal image interpretation.

RADIATION DOSIMETRY

Based on human data, the absorbed radiation dose to an average human adult (70 kg) from an intravenous injection of the agent are listed in Table 9. The values are listed in descending order as rad/mCi and mGy/MBq and assume urinary bladder emptying at 4.8 hours.

Table 9 Estimated Absorbed Radiation Dose

Target Organ	rad/mCi	mGy/MBq
Kidneys	0.33	0.090
Spleen	0.16	0.042
Testes	0.11	0.031
Thyroid Gland	0.088	0.024
Red Marrow	0.078	0.021
Liver	0.078	0.021
Heart wall	0.054	0.014
Bone surface	0.054	0.015
Lungs	0.053	0.014
Adrenal glands	0.044	0.012
Pancreas	0.037	0.010
Urinary bladder	0.033	0.0089
Uterus	0.031	0.0084
Small Intestine	0.019	0.0050
Upper Large Intestine	0.019	0.0050
Ovaries	0.016	0.0042
Lower Large Intestine	0.014	0.0038

Dose calculations were performed using the standard MIRD method (MIRD Pamphlet No. 1 rev., Soc. Nucl. Med., 1976). Effective dose equivalent was calculated in accordance with ICRP 53 (Ann. ICRP 18, 1-4, 1988) and gave a value of 0.023 mSv/MBq (0.084 rem/mCi).

HOW SUPPLIED

Each kit is comprised of one vial containing a sterile, non-pyrogenic, freeze-dried mixture of Depreotide, stannous chloride dihydrate, sodium glucoheptonate dihydrate and edetate disodium dihydrate. Kits are available as individual vials or as packs of five.

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References: 1. NeoTect™ Prescribing Information. 2. Blum JE, Handmaker H, Rinne NA. The utility of a somatostatin-type receptor binding peptide radiopharmaceutical (P829) in the evaluation of solitary pulmonary nodules. *Chest*. 1999;115:224-232. 3. Kazerooni EA, Lim FT, Mikhail A, Martinez FJ. Risk of pneumothorax in CT-guided transthoracic needle aspiration biopsy of the lung. *Radiology*. 1996;198:371-375.

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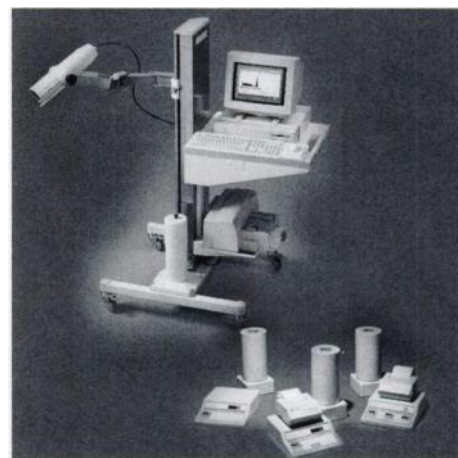
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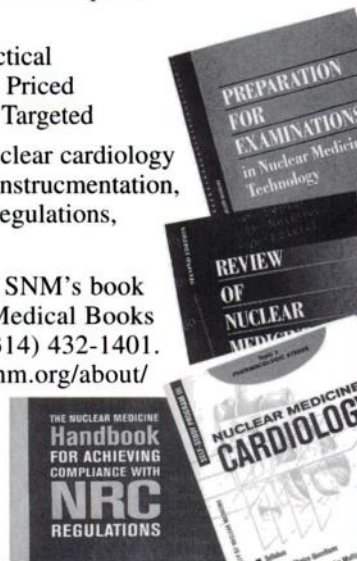
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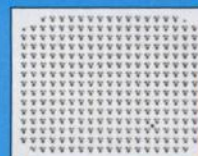
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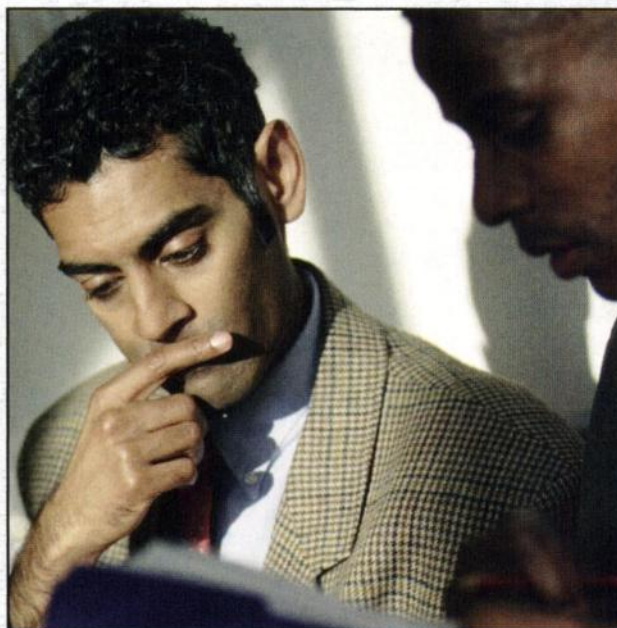
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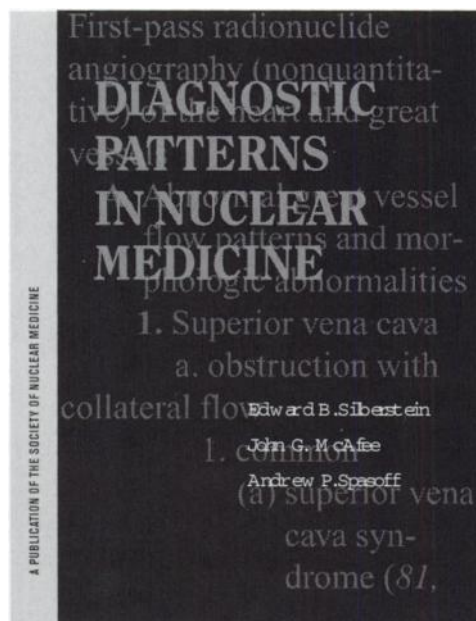


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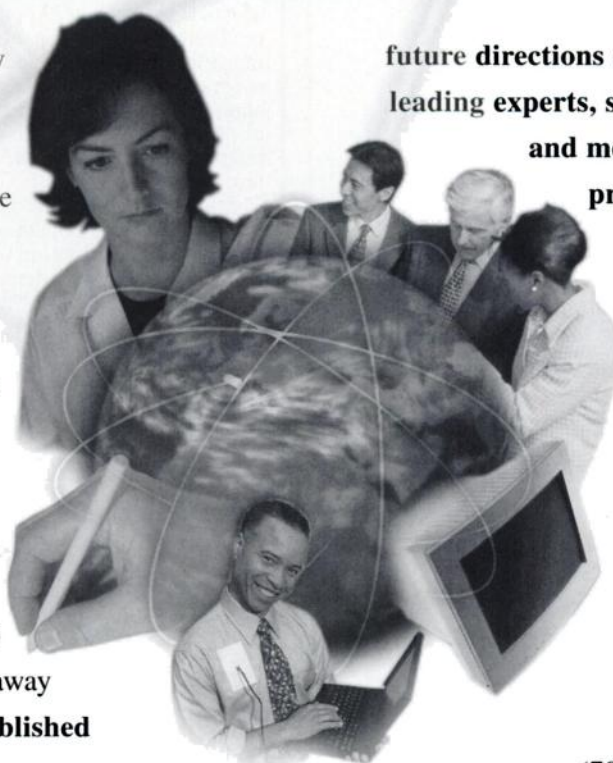
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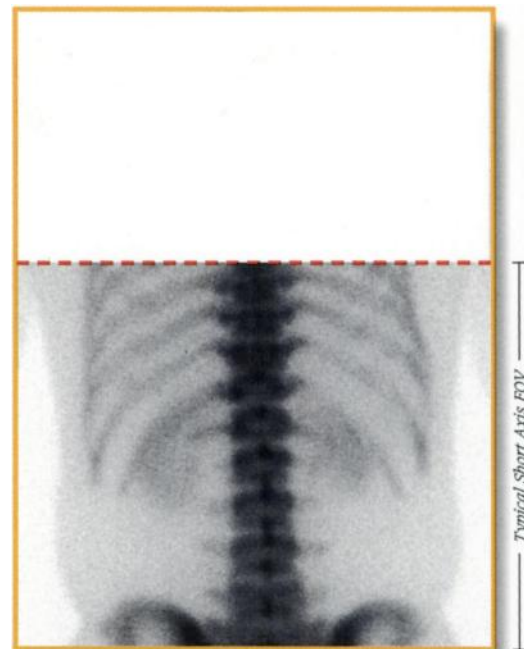
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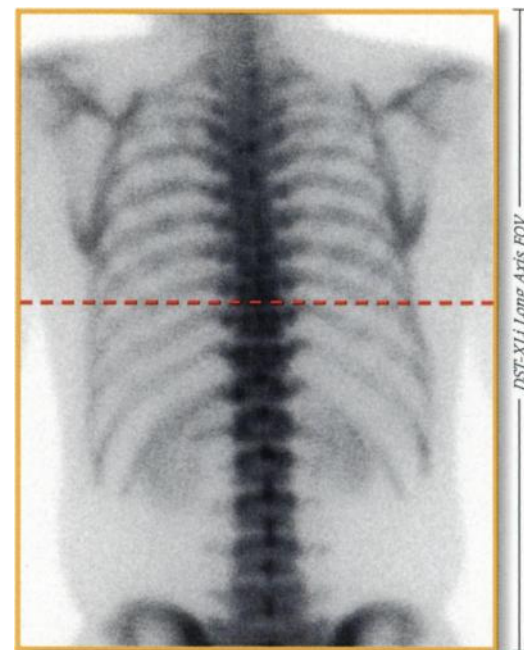
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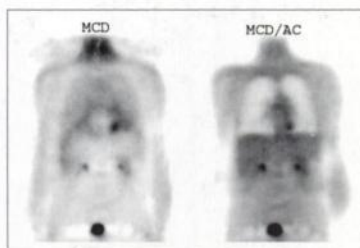


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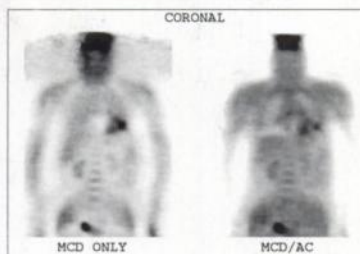
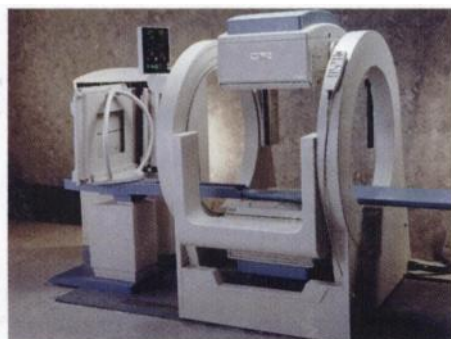


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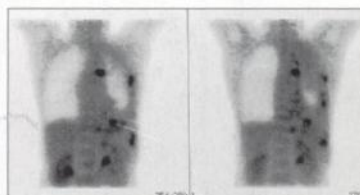
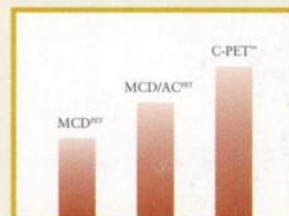


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