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Upon Suspicion of Pulmonary Malignancy

NeoTect™
Kit for the Preparation of Technetium Tc 99m Deproteotide Injection

BOUND TO SEE MORE
Noninvasively Characterizes Pulmonary Masses

NeoTect, a noninvasive nuclear imaging agent, characterizes pulmonary masses as being rich in somatostatin receptors.1,2

- Many malignant pulmonary masses and some inflammatory processes overexpress somatostatin receptors (SSTRs)1
- For use 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

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 NeoTect, like other small peptides, may induce hypersensitivity reactions or anaphylactic reactions. Adequate treatment provisions, including epinephrine, should be available for immediate use.1

Please see brief summary of prescribing information on following page.
Brief Summary of Prescribing Information

DESCRIPTION
NeoTect™ (Kit for the Preparation of Technetium Tc 99m Deproteotide Injection) is intended for use in the in vitro production of Technetium Tc 99m Deproteotide, a diagnostic radiopharmaceutical to be used by intravenous injection. Each vial contains a sterile, non-pyrogenic lyophilized mixture of 50 pg of Deproteotide, 5 mg of sodium glucoheptonate dihydrate, 50 pg of stannous chloride dihydrate (with a minimum stannous content of 15 pg), 100 pg 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 animal or bacterial preservatives.

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 Deproteotide 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 lIgG 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 Deproteotide Injection, like other radioactive drugs, must be handled with care and appropriate safety measures should be used to minimize radiation exposure to the clinician. 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 inadvertent 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), aspartate aminotransferase (AST), blood cell count, and eosinophil count following administration of Technetium Tc 99m Deproteotide Injection.

Drug Interactions
Drug interactions were not noted in clinical studies in which Technetium Tc 99m Deproteotide 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 Deproteotide Injection or with deproteotide were negative: Salmonella/Echerichia 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 Deproteotide Injection. It is not known whether Technetium Tc 99m Deproteotide Injection can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Technetium Tc 99m Deproteotide 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 deproteptide to determine its excretion in human milk. Technetium Tc 99m Deproteotide is excreted in human milk. It is not known whether Technetium Tc 99m Deproteotide Injection is excreted in human milk. Caution should be exercised when Technetium Tc 99m Deproteotide Injection is administered to a nursing woman. Whenever possible, infant formula should be substituted for breast milk if the technetium has been eliminated.

Pediatric Use
Safety and effectiveness of Deproteotide 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 pg of deproteotide. Of these adults, 96% were men and 42% were women. The mean age was 55.0 years (18-88 years).

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

At least one adverse event occurred in 29/447 (6.5%) patients after Technetium Tc 99m Deproteotide 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 Deproteotide Injection.

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

DOSAGE AND ADMINISTRATION
NeoTect™ is administered as a peripheral intravenous injection at a single dose of 15 to 20 mCi containing approximately 50 pg of Technetium Tc 99m radiolabeled Deproteotide 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 Deproteotide Injection are intended only for use in the preparation of Technetium Tc 99m Deproteotide 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 healthy adult (70 kg) from an intravenous injection of the agent is listed in Table 9. The values are listed in descending order as red/24h and mg/MBq and assume urinary bladder emptying at 4.8 hours.

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 0.033 mSv/MBq (0.004 rem/MBq).

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

NDC 64570-511-10 - single vial
NDC 64570-511-05 - five vial pack

STORAGE
Store the kit at ≤10°C (≤ 14°F). Store the reconstituted injection solution at 20-25°C (68-77°F) using appropriate radiation shielding. Use within 5 hours of reconstitution.

The kit should be protected from light.

Distributed by:
Diastec, Inc.
9 Delta Drive
Londonderry, New Hampshire 03053

Revised August 1999


NeoTect™ is a trademark of Diastec, Inc.
Is Your Nuclear Medicine Department Being Left Out Of Your PACS Plan?

Do you have older nuclear medicine systems that aren't DICOM compliant?

DELTAmanager® can interface to all nuclear medicine systems, old and new, then send the data out via DICOMlink™ to your PACS network for display, print or archive.

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After administration of other intravenous drugs, patients with a history of drug reactions, other allergies, or immune system disorders should be observed for several hours.

AcuTect offers a greater measure of confidence, especially in difficult, time-consuming cases of suspected Deep Vein Thrombosis. As the first imaging modality to target acute DVT, AcuTect increases your ability to detect dangerous clots in patients with signs and symptoms. AcuTect represents an option for increased confidence — particularly vs. ultrasound — when you’re faced with difficult patient types, such as the obese, or those with deep iliac clots, immobility, casts, or other constraints. AcuTect finds its target, binding preferentially to the glycoprotein (GP) IIb/IIIa receptors found on activated platelets. And that means rapid and specific detection of acute DVT — with greater throughput.

Clinical follow-up studies of patients with negative AcuTect scans have not been performed to determine if negative image findings mean the absence of acute venous thrombosis. If a patient has clinical signs and symptoms of acute venous thrombosis, a clinical management decision to withhold treatment with anticoagulants should not be based on a negative AcuTect study alone.

After administration of AcuTect, as with the administration of other intravenous drugs, patients with a history of drug reactions, other allergies, or immune system disorders should be observed for several hours.

ACuTect
(Kit for the Preparation of Technetium Tc 99m Aperteide Injection)

The difference is acute.

For more information call 1-877-342-8433 or visit our Web site, www.AcuteTect.com
The difference is acute.
Increase patient throughput—with rapid hepatic clearing, highly efficient MYOVIEW

Give your nuclear department “rapid clearance” capability with MYOVIEW. MYOVIEW clears quickly from the blood, liver, and lungs\(^1\text{,3}\) for quality target-to-background ratios and timely imaging (as soon as 15 minutes or up to 4 hours post-injection).\(^1\) The clearance properties of MYOVIEW allow for highly flexible camera scheduling and enhanced patient management. Any way you look at it, you’re cleared for efficiency with MYOVIEW.

In studying patients with known or suspected coronary artery disease, care should be taken to ensure continuous cardiac monitoring and the availability of emergency cardiac treatment.


MYOVIEW. The image of efficiency.
Kit for the Preparation of Technetium Tc99m Tetrofosmin for Injection
Diagnostic Radiopharmaceutical for Intravenous use only

Please consult full prescribing information before using. A summary follows:

**DESCRIPTION**

The Medi-Physics Myoview kit is supplied as a pack of five vials for use in the preparation of a technetium Tc99m tetrofosmin intravenous injection to be used for the scintigraphic delineation of regions of reversible myocardial ischemia in the presence or absence of infarcted myocardium. Each vial contains a predispensed, sterile, non-pyrogenic, lyophilized mixture of 0.23 mg technetium [99m-Tc]-[Cl4-]-[DIX]-[2-chlo-2-ethoxy-4-(2-dimethylaminoethyl)ethyl] tetraakis(2,3-diaminophenyl)ethylenediamine (Tc99m-DTPA) and 30 μg stannous chloride dihydroxide (minimum stannous tin 5.0 μg; maximum stannous tin and stannic tin 15.8 μg). 0.32 mg disodium stannous chloride and 1.0 mg sodium D-glucuronate, and 1.8 mg sodium carbonate. The lyophilized powder is sealed under a nitrogen atmosphere with a rubber closure. The product contains no antimicrobial preservative.

**CLINICAL PHARMACOLOGY**

**General**

When technetium Tc99m pertechnetate is added to tetrofosmin in the presence of stannous reductant, a lipophilic, cationic technetium Tc99m complex is formed, Tc99m tetrofosmin. This complex is the active ingredient in the reconstituted drug product, on whose biodistribution and pharmacokinetic properties the indications for use depend.

**Clinical Trials**

A total of 252 patients with ischemic heart disease or asymptomatic chest pain who had a reason for exercise stress imaging were studied in two open-label, multi-center, clinical trials of Tc99m tetrofosmin (data on file and study b). Of these 252 patients there were 212 (83%) males and 40 (17%) females with a mean age of 60.5 years (range 33.7 to 82.4 years). At peak exercise, maximum heart rate achieved and peak systolic blood pressure were comparable after Myoview and thallium-201 exercise studies. All patients had exercise and rest planar imaging with Myoview and thallium-201; 191 (76%) patients also had SPECT imaging. The Myoview and thallium-201 images were separated by a mean time of 2.5 days (1-4 days before or 2-14 days after Myoview). For Myoview imaging, adverse events occurred in 185/296 MBq (5-9 MBq) Tc99m tetrofosmin at peak exercise and 555-888 MBq (15-24 MBq) Tc99m tetrofosmin at rest approximately 4 hours later. For thallium-201 imaging, patients received thallium-201 55.5-74.9 MBq (1.5-2.0 MBq) at peak exercise. The images were evaluated for the quality of the image (excellent, good or poor) and the diagnosis (with scores of 0 = normal, 1 = ischemia, 2 = infarct, 3 = mixed infarct and ischemia). The primary outcome variable was the percentage of correct diagnoses in comparison to the final clinical diagnosis. All planar images were blindly read; SPECT images were evaluated by the unblinded investigator. A subset of 181/252 (71%) patients had coronary angiography comparisons to the planar images of Myoview or thallium-201.

**INDICATIONS AND USAGE**

Myoview is indicated for scintigraphic imaging of the myocardium following separate administrations under exercise and resting conditions. It is useful in the delineation of regions of reversible myocardial ischemia in the presence or absence of infarcted myocardium.

**CONTRAINDICATIONS**

None known.

**WARNINGS**

In studying patients with known or suspected coronary artery disease, care should be taken to ensure continuous cardiac monitoring and the availability of emergency cardiac treatment.

**PRECAUTIONS**

**General**

To minimize radiation dose to the bladder, the patient should be encouraged to void when the examination is completed and as often thereafter as possible. Adequate hydration should be encouraged to prevent frequent voiding.

The contents of the Myoview vial are intended only for use in the preparation of technetium Tc99m tetrofosmin injection and are NOT to be administered directly to the patient. As with all injectable drug products, allergic reactions and anaphylaxis may occur.

Sometimes Tc99m labeled myocardial imaging agents may produce planar and SPECT images with different imaging information. Technetium Tc99m tetrofosmin 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 radioisotopes, and whose experience and training have been approved by the appropriate governmental agency authorized to license the use of radioisotopes.

Drug Interactions: Drug interactions were not noted and were not studied in clinical studies in which Myoview was administered to patients receiving concomitant medication. Drugs such as beta blockers, calcium blockers and nitrates may influence myocardial function and blood flow. The effects of such drugs on imaging results are not known.

**Carcinogenesis, Mutagenesis,Impairment of Fertility**

Studies have not been conducted to evaluate carcinogenic potential or effects on fertility. Tetrofosmin, a stannous compound, was mutagenic in vitro in the Ames test, mouse lymphoma, or human lymphocyte tests, nor was it clastogenic in vivo in the mouse micronucleus test.

**Pregnancy Category C**

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

**Nursing Mothers**

Technetium Tc99m pertechnetate can be excreted in human milk. Therefore, formula should be substituted for breast milk until the technetium has cleared from the body of the nursing woman.

**ADVERSE REACTIONS**

**Adverse events** evaluated in clinical trials of 764 adults (511 men and 253 women) with a mean age of 58.7 years (range 29-94 years). The subjects received a mean dose of 7.67 mCi on the first injection and 22.4 mCi on the second injection of Myoview™.

Deaths did not occur during the clinical study period of 2 days. Six cardiac deaths occurred 3 days to 6 months after injection and were thought to be related to the underlying disease or cardiac surgery. After Myoview injection, serious episodes of angina occurred in 3 patients.

Overall cardiac adverse events occurred in 576 kids (less than 1%) of patients after Myoview injection.

The following events were noted in less than 1% of patients:

- Cardiovacular: angina, hypertension, Torasol Tables
- Gastrointestinal: vomiting, abdominal discomfort
- Hypersensitivity: cutaneous allergy, hypotension, dyspnea
- Special Senses: metallic taste, burning of the mouth, smelling something

There was a low incidence (less than 4%) of a transient and clinically insignificant rise in white blood cell counts following administration of the agent.

**DOSAGE AND ADMINISTRATION**

For exercise and rest imaging, Myoview is administered in two doses:

- The first dose of 5 mCi (185-296 MBq) is given at peak exercise.
- The second dose of 15-24 mCi (555-888 MBq) is given approximately 4 hours later, at rest. Imaging may begin 15 minutes following administration of the agent.

Dose adjustment has not been established in renal or liver impaired, pediatric or geriatric patients.

**RADIATION DOSEMISTRY**

Based on human data, the absorbed radiation doses to an average human adult (70 kg) from intravenous injections of the agent under exercise and resting conditions are listed in the following table. The values are listed in descending order as rad/mCi and μGy/MiBql and assume urinary bladder emptying at 3.5 hours.

**Estimated Absorbed Radiation Dose (Technetium Tc99m Tetrofosmin Injection)**

<table>
<thead>
<tr>
<th>Target organ</th>
<th>Exercise</th>
<th>Rest</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gall bladder wall</td>
<td>0.123</td>
<td>0.090</td>
</tr>
<tr>
<td>Upper large intestine</td>
<td>0.075</td>
<td>0.030</td>
</tr>
<tr>
<td>Bladder wall</td>
<td>0.056</td>
<td>0.071</td>
</tr>
<tr>
<td>Lower large intestine</td>
<td>0.057</td>
<td>0.082</td>
</tr>
<tr>
<td>Small intestine</td>
<td>0.045</td>
<td>0.093</td>
</tr>
<tr>
<td>Kidney</td>
<td>0.029</td>
<td>0.046</td>
</tr>
<tr>
<td>Salivary glands</td>
<td>0.003</td>
<td>0.043</td>
</tr>
<tr>
<td>Ovaries</td>
<td>0.029</td>
<td>0.035</td>
</tr>
<tr>
<td>Uterus</td>
<td>0.027</td>
<td>0.031</td>
</tr>
<tr>
<td>Bone surface</td>
<td>0.022</td>
<td>0.021</td>
</tr>
<tr>
<td>Pancreas</td>
<td>0.019</td>
<td>0.018</td>
</tr>
<tr>
<td>Stomach</td>
<td>0.017</td>
<td>0.017</td>
</tr>
<tr>
<td>Thyroid</td>
<td>0.016</td>
<td>0.022</td>
</tr>
<tr>
<td>Adrenals</td>
<td>0.016</td>
<td>0.015</td>
</tr>
<tr>
<td>Heart wall</td>
<td>0.015</td>
<td>0.015</td>
</tr>
<tr>
<td>Red marrow</td>
<td>0.015</td>
<td>0.015</td>
</tr>
<tr>
<td>Spleen</td>
<td>0.015</td>
<td>0.014</td>
</tr>
<tr>
<td>Muscle</td>
<td>0.013</td>
<td>0.012</td>
</tr>
<tr>
<td>Tissues</td>
<td>0.013</td>
<td>0.011</td>
</tr>
<tr>
<td>Liver</td>
<td>0.012</td>
<td>0.012</td>
</tr>
<tr>
<td>Thymus</td>
<td>0.012</td>
<td>0.009</td>
</tr>
<tr>
<td>Brain</td>
<td>0.010</td>
<td>0.008</td>
</tr>
<tr>
<td>Lungs</td>
<td>0.008</td>
<td>0.008</td>
</tr>
<tr>
<td>Skin</td>
<td>0.008</td>
<td>0.007</td>
</tr>
</tbody>
</table>

Dose calculations were performed using the standard MIRD method (NIRD Pamphlet No. 1 (rev), Society of Nuclear Medicine, 1976). Effective dose equivalents (EDE) were calculated in accordance with ICRP 53 (Ann. ICRP 18 (1-4), 1986) and gave values of 8.61 × 10⁵ mSV/MBiQ and 1.12 × 10⁷ mSV/MBiQ after exercise and rest, respectively.

**Manufactured by:**

Nycomed Amersham plc
Amersham United Kingdom

Patent No. 5,045,302 (T)

**Distributed by:**

Medi-Physics, Inc.,
Arlington Heights, IL 60004
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Circle Reader Service No. 135

Revised December 1998

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INTRODUCING

Hawkeye

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Localization of disease has long remained an elusive diagnostic factor — until now.

The Millennium VG Hawkeye not only detects the presence of disease, it utilizes Functional Anatomic Mapping to identify its location. Never before has there been such a superb blending of imaging function and form. By merging the functional imaging of PET and SPECT with the anatomical landmarks of CT, Hawkeye provides you with powerful diagnostic information.

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See your way clear

Decisive information keeps you on course

Guiding you to optimal intervention for neuroendocrine tumors

- Somatostatin receptor scintigraphy with OctreoScan detects and localizes primary tumors and metastatic spread often missed by conventional imaging (sensitivity varies 61%-100%, depending on tumor type).1
- Whole-body scanning can more definitively confirm the extent of disease.
- You are better able to
  - 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.
BRIEF SUMMARY OF PRESCRIBING INFORMATION

DESCRIPTION
OctreoScan® is a kit for the preparation of indium-111 pentetreotide, a diagnostic radiopharmaceutical. It is a kit consisting of two components:
1. A 10-mL OctreoScan Reaction Vial which contains a lyophilized mixture of 10 μg of pentetreotide.
2. A 10-mL vial of Indium-111 Chloride Sterile Solution.
Indium-111 pentetreotide is prepared by combining the two kit components.

INDICATIONS AND USAGE
Indium-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 GLYCOSE OCTREOTIDE CONJUGATE MAY FORM.

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

PRECAUTIONS
General
1. Therapy with octreotide acetate can produce severe hypersensitivity in patients with insulinomas. Since pentetreotide is an analog of octreotide, an intravenous line is recommended in any patient suspecting of having an insulinoma. An intravenous solution containing glucose should be administered just before and during administration of indium-111 pentetreotide.
2. The contents of the two vials supplied with the kit are intended only for use in the preparation of indium-111 pentetreotide and are NOT to be administered separately to the patient.
3. Since indium-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-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 who have been given a mild laxative (e.g., bisacodyl or lactulose) be asked to void and administer of indium-111 pentetreotide (see Dosage and Administration section).
5. Indium-111 pentetreotide should be tested for labeling yield of radioactivity prior to administration. The product must be used within 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-111 pentetreotide.
7. Octreotide acetate and the natural somatostatin hormone may be associated with cholecystasis, presumably by allowing fat absorption and possibly by decreasing motility of the gallbladder. A single dose of indium-111 pentetreotide is not expected to cause cholecystasis.
8. As with any other radiopharmaceutical, 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.

Carbohydrate, Mutagenesis, Impairment of Fertility
Studies have not been performed with indium-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 in an in vivo mouse micronucleus assay; evidence of mutagenicity was not found.

Pregnancy Category C
Animal reproduction studies have not been conducted with indium-111 pentetreotide. It is not known whether indium-111 pentetreotide can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Therefore, indium-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-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 bronchitis, anaphylaxis, and one case of decreased hematoct 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-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, labelled 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 intake is necessary during the period as a support both to renal elimination and the bowel-clearing process. In a patient with an insulinoma, bowel-clearing should be undertaken only after consultation with an endocrinologist.

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

The dose should be confirmed by a suitably calibrated radionuclide counting chamber immediately before administration. As with all intravenously administered products, OctreoScan should be injected 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 Kennngton, et al.2

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

<table>
<thead>
<tr>
<th>PLANAR</th>
<th>SPECT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kidneys</td>
<td>54.16</td>
</tr>
<tr>
<td>Liver</td>
<td>12.15</td>
</tr>
<tr>
<td>Spleen</td>
<td>73.86</td>
</tr>
<tr>
<td>Urine</td>
<td>6.34</td>
</tr>
<tr>
<td>Ovaries</td>
<td>4.69</td>
</tr>
<tr>
<td>Testes</td>
<td>2.90</td>
</tr>
<tr>
<td>Rectal</td>
<td>3.46</td>
</tr>
<tr>
<td>Bladder</td>
<td>30.42</td>
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<tr>
<td>Stomach</td>
<td>5.67</td>
</tr>
<tr>
<td>Small Intestine</td>
<td>4.78</td>
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<tr>
<td>Upper Large Intestine</td>
<td>5.90</td>
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<tr>
<td>Lower Large Intestine</td>
<td>7.73</td>
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<tr>
<td>Adrenals</td>
<td>7.55</td>
</tr>
<tr>
<td>Thyroid</td>
<td>7.43</td>
</tr>
</tbody>
</table>

Effective Dose Equivalent
13.03 1.03 26.06 2.61

1. Values listed include a correction for a maximum of 0.1% indium-111 radiometric contamination at calibration.


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 019-9060-49, is supplied with the following components:
1. A 10-mL OctreoScan Reaction Vial which contains a lyophilized mixture of (i) 10 μg pentetreotide [N-(dehydroalanine)]-N,N,N',N'-octadecyl-D,L-phenylalanyl-L-hemicyclohexyl-L-phenylalanyl-D,L-phenylalanyl-L-lysyl-L-threonyl-L-hemicycloheXyl-L-threoninol (2-7) desaline (also known as octreotide DTPA), (ii) 2.5 mg gentamic acid [2,5-dihydroxybenzoic acid], (iii) 4.9 mg trisodium citrate, anhydrous, (iv) 0.37 mg citric acid, anhydrous, and (v) 1.0 mg sodium.

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

2. A 10-mL vial of Indium-111 Chloride Sterile Solution, which contains 1.1 mL of 111 MBq/mL (0.03 mCi/mL) indium-111 chloride is 0.02 N HCl at time of calibration. The vial also contains lactose at a concentration of 3.5 g/kg (lactose, 1.2 g/mL). The final contents are sterile and nonpyrogenic. No bacteriostatic preservative is present.

In addition, the kit also contains the following items: (1) a 25 g x 1/4" needles (B-D, Monoject) used to transfer Indium-111 Chloride Sterile Solution to the OctreoScan Reaction Vial, (2) a pressure sensitive label, and (3) a package insert.

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Mallinckrodt Nuclear Medicine Division
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Or order online at [www.snm.org/about/catalog.html](http://www.snm.org/about/catalog.html)

**SOCIETY OF NUCLEAR MEDICINE**
Nuclear Medicine Week gives you the opportunity to educate potential patients, referring physicians and your community about the history, value and safety of nuclear medicine. We have posters, balloons, buttons and much more to help you decorate your office, lunchroom and department to promote your specialty. Hand out this year's themes' pens, pencils and pads of paper to referring physicians, nurses and administrators in your hospital and/or institutions. If you are a nuclear medicine industry partner use these items to thank your valued customers.

Keep the celebration alive all year long! Promoting nuclear medicine does not need to be limited to Nuclear Medicine Week. Take advantage of every opportunity throughout the year to increase the understanding and utilization of nuclear medicine.
**ORDERING INFORMATION** (Note: All orders must be accompanied with this order form.)

Pre-payment via check, VISA or Mastercard required for all orders.

**Fax:** 913-362-7401  **Call Toll Free:** 800-829-7062

**Mail:** MidPoint National  
Attn: Society of Nuclear Medicine  
P.O. Box 411037, Kansas City, MO 64141-1037

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<th>ITEM</th>
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<th>TOTAL</th>
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<td>________ packs</td>
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<td></td>
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<tr>
<td>Pens (Red)</td>
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<tr>
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<td>Balloons (Red)</td>
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**SUBTOTAL:**

Shipping: (allow 2-4 weeks for delivery)

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$20.01-$30.01 add $8.00  
$30.00 or more add $12.00

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**TOTAL:**

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Card Holder’s Name: ___________________________

Card Holder’s Signature: _______________________

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Address: ___________________________

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Positions Wanted

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The Cleveland Clinic Foundation has a position available for a full-time Nuclear Medicine Physician. The Cleveland Clinic provides research and clinical facilities, including a radiology residency program, a PET center and a full complement of nuclear imaging capabilities. Expertise in neurologic nuclear applications valuable. For further details, please contact: Donald R. Neumann, MD, PhD, Department of Nuclear Medicine (G63), Cleveland Clinic Foundation, 9500 Euclid Ave., Cleveland, OH 44195. E-mail: don@ucmed.ccf.org. Fax: (216) 444-3943.

Nuclear Medicine Physician-United Kingdom
A full-time position in Nuclear Medicine is available. Currently there are 5 Nuclear Medicine physicians (3 full-time and 2 part-time) providing Nuclear Medicine services in two hospitals. The hospitals are located in New Westminster, British Columbia and Burnaby, British Columbia. Qualified candidates must be licensed or eligible for licensure with the BC College of Physicians and Surgeons and must hold specialist qualifications in Nuclear Medicine from the Royal College of Physicians and Surgeons of Canada. Both hospitals are in close proximity to Vancouver and enjoy easy access to ocean and fresh water beaches, mountains, forests and urban amenities.

Excellent and diverse educational, business, cultural and recreational activities abound. Interested parties should forward a curriculum vitae and letter of interest to Dr. E. G. Director, Nuclear Medicine, Royal Columbian Hospital, 330 East Columbia St., New Westminster, BC V3L 3W7. Phone: (604) 520-4540. Fax: (604) 520-4444.

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Nuclear Imaging-Pittsburgh, PA
ABR-Certified Radiologist with ABMN Certification or ABR special competence in Nuclear Radiology sought for busy private practice at university affiliated hospital. Experience in nuclear cardiology a must. Capabilities in cross-sectional imaging and general radiology also required. Immediate availability. Please submit cover letter, CV and references to: C.R. Jarnolowski, MD, Department of Radiology, UPMC Shadyside Hospital, 5200 Centre Avenue, Pittsburgh, PA 15232.

PET Imaging Manager
American Diagnostic Medicine seeks board certified nuclear medicine technologist with 5+ years experience as a working manager to oversee the first PET Imaging Center in the Brooklyn area. Experience in management and knowledge of state regulations required. Must work well with ancillary staff members. Competitive salary & benefits. Please fax resume to: Janet Kotek at (630) 834-7115 or call (800) 262-9645 x109.

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American Diagnostic Medicine, Inc. seeks board certified nuclear medicine technologist with 2+ years experience. Positions immediately available in Sterling Heights, ML. Above average salary, bonus and benefits. Experience with ADAC, GE, or PET camera a plus. Please fax resume to: 630-834-7115, or call 800-262-9645 x109, Janet Kotek.

Nuclear Medicine Technologist
American Diagnostic Medicine, Inc. seeks board certified nuclear medicine technologist with 2+ years experience. Position immediately available in Chicago, IL. Above average salary, bonus and benefits. Experience with ADAC, Gen Peg camera a plus. Please fax resume to: 630-834-7115, or call 800-262-9645 x109, Janet Kotek.

Cardiac Nuclear Medicine Technologist-Part Time
Private Nuclear Cardiology Facility in Rockland County, NY has a part time position available. Experience preferred. Must have complete knowledge of gated cardiac SPECT imaging. GE experience a plus. Must be NY State Licensed and AART or NMTCB Certified. Please fax resume to Sue Kushner: (914) 942-1431.

Director of Nuclear Cardiology/ PET Medicine
Buffalo Cardiology & Pulmonary Associates, P.C., a busy practice located in Western New York, is currently seeking a board certified cardiologist to serve as Director of Nuclear Cardiology/PET Medicine. Candidates must have experience (or be willing to train) in PET technology, administration of day-to-day operations, directing research, and a strong interest in cardiac PET applications. Nuclear license required. Excellent opportunity with partnership potential.

Please send CV to:
Samuel Iacuzzo
Human Resources Department
Buffalo Cardiology & Pulmonary Associates, P.C.
5305 Main Street
Williamsville, NY 14221
Fax: (716) 565-6678

Nuclear Medicine Supervisor
Bay Area Medical Center, a 115-bed general acute care facility, is currently seeking a candidate to supervise all aspects of the nuclear medicine department. Responsibilities include supervising scheduling and supervising staff, as well as maintaining the records pertaining to NRC regulations.

The two-camera Nuclear Medicine Department serves 1,700 patients per year. Candidate will work Monday through Friday in this exempt position and rotate call every third weekend.

Qualifications include graduate of an AMA-approved School of Nuclear Medicine, NMTCB or ARRT(N) certification preferred. Preference will be given to candidates with a Bachelor's degree and a minimum of three years staff tech experience.

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Nuclear Medicine Technologist

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To find out more about YRMC, please call 1-800-722-YUMA or email or fax your resume to: Yuma Regional Medical Center, Professional Staff Coordinator, 2400 Avenue A, Yuma, Arizona 85364. Fax: (520) 344-1404

To learn more about the YRMC experience, please visit: www.yumanregional.org
NUCLEAR MEDICINE CARDIOLOGIST

The Brigham and Women's Hospital, Division of Nuclear Medicine, Department of Radiology is seeking a full-time Nuclear Medicine Cardiologist.

Candidates should be certified by the American Board of Nuclear Medicine and have at least two years of practical experience in all aspects of nuclear cardiology including the management of stress exercise testing and pharmacological interventions. Primary responsibility is in clinical nuclear cardiology. The division provides both clinical and laboratory research opportunities. Job includes liaison with cardiologists and with multidisciplinary colleagues in the field of cardiac imaging. Secondary responsibilities include sharing on the coverage of general nuclear medicine.

Interested candidates should send CV and letter of interest to:
S. Ted Treves, MD, Chief
Division of Nuclear Medicine, Department of Radiology
Brigham and Women's Hospital
75 Francis Street
Boston, MA 02115
Phone: (617) 355-7935

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TECHNICAL DIRECTOR, NUCLEAR MEDICINE

The Brigham and Women's Hospital, Division of Nuclear Medicine, Department of Radiology is seeking a full-time Technical Director.

Candidates must be certified in nuclear medicine technology (CNMT) and should have three to five years experience in a busy nuclear medicine service covering all aspects of the field including nuclear cardiology. Experience on coincidence systems or PET would be a plus, but is not mandatory. Technical Director reports to the Chief of the Division and is responsible for all operational, budgetary, safety, educational and regulatory aspects of the division. Technical Director will ensure a compassionate, high quality, effective and efficient operation of the clinical service.

Interested candidates should send CV and letter of interest to:
S. Ted Treves, MD, Chief
Division of Nuclear Medicine, Department of Radiology
Brigham and Women's Hospital
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M K E A D I F F E R N C E.

NUCLEAR MEDICINE TECHNOLOGIST

Hahnemann University Hospital is currently seeking a Nuclear Medicine Technologist for its Nuclear Cardiology Department. The successful applicant will perform all nuclear cardiology imaging and dosing procedures according to NRC, JCAHO, and laboratory standards for quality and methodology. The selected candidate will be a graduate of an approved nuclear medicine technology training program with certification or certification eligibility by one of the nuclear medicine certifying agencies. Basic Life Support Certification required. Previous experience as a staff technologist preferred.

For immediate consideration, please fax resume to: (215) 763-3106 or mail to: Hahnemann University Hospital, Broad & Vine Streets, MS 371, Philadelphia, PA 19102.

For more information and other opportunities, please visit us on the web at: www.teamstaest.com.

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Members and nonmembers are invited to submit papers for publication in the JNM. Papers reporting results from clinical and research investigations of all specialties are welcome. Brief communications detailing preliminary research results in an abridged paper are especially desired. JNM is indexed in Index Medicus and in MEDLINE.

Information for authors is available at: www.snm.org/pdf/infoauth_999.pdf

Please forward submissions to:

Martin P. Sandler, MD
The Journal of Nuclear Medicine
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Berlex Imaging understands your drive to enhance diagnostic and therapeutic performance to deliver your patients the highest level of care. Sharing these same goals, Berlex Imaging has recently created an alliance to raise the level of excellence in nuclear medicine imaging and therapy. Each partner brings a variety of strengths to this alliance:

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- **Diatide** has pioneered innovative peptide engineering and technetium radiolabeling chemistry, producing “smart drug” technology to “find-fight-follow”™ disease.
- **CIS-US** is a leading supplier of traditional radiopharmaceuticals for the diagnosis and treatment of tumor pathologies and diseases of major organ systems.

**Furthering Our Commitment to Nuclear Medicine**
This new alliance, under the Berlex Imaging name, is committed to continued advancements in nuclear medicine diagnostics and therapies. Berlex Imaging is dedicated to bringing you “everything you need to see,” from radiology to nuclear medicine, and beyond.

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**AutoQUANT™**
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