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FAX: (201) 825-4829
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Upon Suspicion of Pulmonary Malignancy

NeoTect™
Kit for the Preparation of Technetium Tc 99m Deproteid 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.

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40-4300000580A
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 diphosphate, 50 μg of stannous chloride diphosphate (with a minimum stannous tin content of 15 μg), 190 μg edetate disodium diphosphate, 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 Perchlorate 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 IGF-I or IGF production 3 weeks following injection. Other immune parameters such as eosinophils, other immunoglobulins, complement, lymphocytes 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 in 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 infants and small children to minimize the risk of radioactive contamination of clothing, bedding, 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 8 oz. of water prior to drug administration. To help protect the patient 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), white blood cell count, and eosinophil count following administration of Technetium Tc 99m Depreotide Injection.

Drug Interactions
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 genotoxic studies with decayed Technetium Tc 99m Depreotide Injection or with depreotide 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 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 Perchlorate 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. Whenever 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, 96% were men and 42% were women. The mean age was 59.0 years (18-86 years).

Dexetha 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>
<thead>
<tr>
<th>Adverse Event (%)</th>
<th>Number of Patients Exposed</th>
<th>Number of Patients with At Least One Adverse Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>7.1%</td>
<td>87</td>
</tr>
</tbody>
</table>

Other adverse events which occurred in < 0.5% of patients following administration of Neotect™ included: arthrosis, back pain, chest pain, diarrhoea, fatigue, gait abnormality, glaucoma, hemoptysis, hypoglycaemia, 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 should be drawn from each reconstructed 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 rd/mCi and mGy/Mbq and assume urinary bladder emptying at 4.8 hours.

### Table 9: Estimated Absorbed Radiation Dose

<table>
<thead>
<tr>
<th>Organ</th>
<th>rd/mCi</th>
<th>mGy/Mbq</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kidney</td>
<td>0.33</td>
<td>0.001</td>
</tr>
<tr>
<td>Spleen</td>
<td>0.16</td>
<td>0.002</td>
</tr>
<tr>
<td>Testes</td>
<td>0.11</td>
<td>0.002</td>
</tr>
<tr>
<td>Thyroid Gland</td>
<td>0.089</td>
<td>0.001</td>
</tr>
<tr>
<td>Liver</td>
<td>0.078</td>
<td>0.001</td>
</tr>
<tr>
<td>Heart</td>
<td>0.054</td>
<td>0.001</td>
</tr>
<tr>
<td>Lung</td>
<td>0.054</td>
<td>0.001</td>
</tr>
<tr>
<td>Adrenal glands</td>
<td>0.044</td>
<td>0.001</td>
</tr>
<tr>
<td>Pancreas</td>
<td>0.037</td>
<td>0.001</td>
</tr>
<tr>
<td>Urinary bladder</td>
<td>0.003</td>
<td>0.001</td>
</tr>
<tr>
<td>Uterus</td>
<td>0.003</td>
<td>0.001</td>
</tr>
<tr>
<td>Small Intestine</td>
<td>0.019</td>
<td>0.005</td>
</tr>
<tr>
<td>Large Intestine</td>
<td>0.019</td>
<td>0.005</td>
</tr>
<tr>
<td>Ovary</td>
<td>0.016</td>
<td>0.004</td>
</tr>
<tr>
<td>Lower/Large Intestine</td>
<td>0.014</td>
<td>0.002</td>
</tr>
</tbody>
</table>

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 (0.064 rem/Mc).

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

**NDC 64570-511-00 - 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.

**Rx Only**

**Distributed by:**

Diatex, Inc.

9 Delta Drive

London, New Hampshire 03053

Revised August 1999

**References:**

Neotect™ is a trademark of Diatex, Inc.

**EXPANDING YOUR VISION**

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It may not be apparent but he's only inches from disaster.

It may not be apparent but he's only inches from disaster.

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) lib/lla 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.

The difference is acute.

AcuTect (Kit for the Preparation of Technetium Tc 99m Apicotide Injection)
ADVERSE REACTIONS

Adverse events were evaluated in clinical studies of 642 adults who received tecturnium Tc 99m in 20.0 mCi labeled to approximately 70-100 μg of biotinophosphate. Of these, 46% were women and 54% men. The mean age was 50.7 years (17 to 85 years). In all patients, adverse events were monitored for at least 3 hours. In a subset of 109 patients, adverse events were monitored for 24 hours. Deaths did not occur during the clinical study period. Following injection of tecturnium Tc 99m apratide, a serious episode of hypotension occurred in one patient who had acute hypertension that began within 10 minutes of injection and, over 80 minutes, progressed to a systolic pressure of 70 mm Hg. At least one adverse event occurred in 92/94 (95.4%) of patients after tecturnium Tc 99m injection. Pain was the most commonly reported adverse event (1.7% of patients or healthy volunteers). Table 1 lists adverse events reported in 0.5% or more of patients who received tecturnium Tc 99m apratide.

### Table 1: ADVERSE EVENTS REPORTED IN ≥0.5% OF PATIENTS FOLLOWING ACUTECT® ADMINISTRATION IN CLINICAL STUDIES

<table>
<thead>
<tr>
<th>Event</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urinary bladder pain</td>
<td>0.5%</td>
</tr>
<tr>
<td>Headache</td>
<td>1.7%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>5.0%</td>
</tr>
<tr>
<td>Other</td>
<td>0.5%</td>
</tr>
</tbody>
</table>

Other adverse events which occurred in ≤0.5% of patients following receipt of AcuTect® included: agitation, asthenia, bradycardia, cardiovascular disorder, chills, convulsions, dizziness, fever, hypotension, injection site reaction, liver enzyme elevation, nausea, palpitations, pruritis, sweat, tachycardia, swelling, and vomiting.

### DOSAGE AND ADMINISTRATION

To detect acute venous thrombosis in a lower extremity, reconstituted AcuTect® should be administered as a peripheral intravenous injection in an extremity, at a dose of approximately 100 μg of biotinophosphate radiolabeled with 20 mCi of technetium 99m. Technetium Tc 99m apratide should be drawn into the syringe and administered using sterile technique. If nondisposable equipment is used, scrupulous care should be taken to prevent residual contamination with traces of cleansing agents. Unused portions of the drug must be discarded appropriately. (See Instructions for Preparation Section of Full Product Information.)

### Linear Extremity Imaging

AcuTect® imaging should begin between 10 and 60 minutes after injection. Patients should void just before imaging in order to limit the influence of urinary bladder radioactivity since technetium Tc 99m apratide is cleared by the kidney. If it is determined that imaging needs to be repeated, additional images may be obtained up to 180 minutes within the same imaging session. The safety of more than one dose has not been established.

Positive AcuTect® uptake in the deep venous structures is defined as asymmetric vascular uptake with or without superimposed diffuse uptake in contrast enhanced images, and asymmetry in both anterior and posterior projections. If asymmetry appears only after extreme contrast enhancement, then diffuse asymmetry must also be present for scoring an image as positive. Superficial increased uptake is not to be interpreted as acute deep venous thrombosis.

### RADIATION DOSIMETRY

Based on human data, the absorbed radiation doses to an average adult (70 kg) from an intravenous injection of technetium Tc 99m apratide are listed in Table 2. The values are listed in descending order as rd/mCi and mgY/mBq and assume urinary bladder emptying at 4.8 hours.

### Table 2: Radiation Absorbed Doses for a 70 Kg Adult

<table>
<thead>
<tr>
<th>Target Organ</th>
<th>Radiation Dose (rd/mCi)</th>
<th>Radiation Dose (mgY/mBq)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urinary Bladder Wall</td>
<td>0.22</td>
<td>0.089</td>
</tr>
<tr>
<td>Kidneys</td>
<td>0.050</td>
<td>0.014</td>
</tr>
<tr>
<td>Upper Large Intestinal Wall</td>
<td>0.039</td>
<td>0.010</td>
</tr>
<tr>
<td>Lower Large Intestinal Wall</td>
<td>0.007</td>
<td>0.001</td>
</tr>
<tr>
<td>Lungs</td>
<td>0.014</td>
<td>0.0092</td>
</tr>
<tr>
<td>Thyroid Gland</td>
<td>0.002</td>
<td>0.0009</td>
</tr>
<tr>
<td>Testes/Ovaries</td>
<td>0.025/(0.023)</td>
<td>0.005/(0.006)</td>
</tr>
<tr>
<td>Red Marrow</td>
<td>0.001</td>
<td>0.00006</td>
</tr>
<tr>
<td>Breasts</td>
<td>0.000</td>
<td>0.000013</td>
</tr>
</tbody>
</table>

Dose calculations were performed using the standard MRD method (MIRD Pamphlet No. 1 rev., Soc. Nucl. Med., 1978). Effective dose equivalent was calculated in accordance with ICRP 53 (Ann. ICRP 19, 1-4, 1990) and gave a value of 0.0059/mCi (0.00054/mBq) and assumed urinary bladder emptying at 4.8 hours.

### HOW SUPPLIED

Each kit contains one vial containing a sterile, nonpyrogenic, freeze-dried mixture of biotinophosphate, stannous chloride and sodium gluconate, and sodium hydrogen carbonate, with a package insert and adverse event reporting kits. Kits are available in packages of 5 vials.

Storage

Store the kit in a refrigerator at 2 to 8°C (36 to 46°F). Store the reconstituted solution injection at 20-25°C (68 to 77°F), using appropriate radiation shielding, for up to 6 hours.

### The difference is acute.

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As a specialist in nuclear medicine, you understand the value that partnering can bring to your patients. Combining your knowledge and experience with the right equipment, products, and supplies, you create a synergy of elements that offers the best chance for successful diagnosis and treatment.

**Synergy for Better Patient Care**

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:

- **Berlex Imaging** introduced the first MRI intravenous contrast agent and is the undisputed market leader. Central to the philosophy at Berlex Imaging is personal involvement in the fields it serves, as evidenced by its outstanding record of continuing education and customer service programs.
- **Diatide** has pioneered innovative peptide engineering and technetium radiolabeling chemistry, producing “smart drug” technology to “find-fight-follow”™ disease.
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**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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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.
Pediatric Use
Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS

Adverse events were evaluated in clinical trials of 704 adults (511 men and 253 women) with a mean age of 59.7 years (range 29-84 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 8 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 576/4 (less than 1%) of patients after Myoview injection.

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

- Cardiovascular: angina, hypertension, Torasdes de Pointes
- 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 5-8 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 DOSIMETRY

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 mCi and MBq 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</td>
<td>0.123</td>
<td>0.180</td>
</tr>
<tr>
<td>Upper large intestine</td>
<td>0.075</td>
<td>0.113</td>
</tr>
<tr>
<td>Bladder wall</td>
<td>0.058</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>0.063</td>
</tr>
<tr>
<td>Kidney</td>
<td>0.039</td>
<td>0.046</td>
</tr>
<tr>
<td>Salivary glands</td>
<td>0.020</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>0.025</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>Renal nucellar</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>Testes</td>
<td>0.013</td>
<td>0.011</td>
</tr>
<tr>
<td>Liver</td>
<td>0.012</td>
<td>0.015</td>
</tr>
<tr>
<td>Thymus</td>
<td>0.012</td>
<td>0.011</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>
<tr>
<td>Breasts</td>
<td>0.008</td>
<td>0.007</td>
</tr>
</tbody>
</table>

Dose calculations were performed using the standard MIRD method (MIRD Pamphlet No. 1 (rev). Society of Nuclear Medicine, 1976). Effective doses equivalents (EDE) were calculated in accordance with ICRP 53 (Ann. ICRP 18 (1-4), 1989) and gave values of 0.61 x 10^7 mSV/MBq and 1.12 x 10^7 mSV/mCi after exercise and rest, respectively.

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  - 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.

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BRIEF SUMMARY OF PRESCRIBING INFORMATION

DESCRIPTION
OctreoScan® is a kit for the preparation of indium in-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 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) ADIMIXTURES OR INJECT INTO TPN INTRAVENOUS ADMINISTRATION LINES. IN THESE SOLUTIONS, A COMPLEX GLUCOSE, 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 the 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 must be tested for labeling yield of radioactivity prior to administration. The product must be used within 6 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 cholestatic jaundice, presumably by altering biliary absorption and possibly by decreasing motility of the gallbladder. A single dose of indium in-111 pentetreotide is not expected to cause cholestasis.
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. Radiochemists should be used by only those physicians who are qualified by specific training in the safe use and handling of radiocolloids.

Cardiogogenesis, Mutagenesis, Impairment of Fertility
Studies have not been performed with indium in-111 pentetreotide to evaluate cardiogenic 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 reproductive capability. 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 533 patients: dizziness, feeling of weakness, headache, hypotension, changes in liver enzymes, joint pain, nausea, swelling, and weight gain. These adverse effects were transient. Also, in clinical trials, there was one reported case of bronchitis 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, 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 this 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 dose for Indium in-111 pentetreotide is a 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 counting chamber immediately before administration.

As with all intravenously administered products, OctreoScan should be injected slowly 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.

Aspects of 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 doses 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 Kneen, et al.

Estimated Absorbed Radiation Doses after Intravenous Administration of Indium in-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>Uretus</td>
<td>6.34</td>
</tr>
<tr>
<td>Oesophagus</td>
<td>4.88</td>
</tr>
<tr>
<td>Tests</td>
<td>2.90</td>
</tr>
<tr>
<td>Red Mucro</td>
<td>3.46</td>
</tr>
<tr>
<td>Urinary Bladder Wall</td>
<td>20.42</td>
</tr>
<tr>
<td>Stomach Wall</td>
<td>5.67</td>
</tr>
<tr>
<td>Small Intestine</td>
<td>4.78</td>
</tr>
<tr>
<td>Upper Intestine</td>
<td>5.80</td>
</tr>
<tr>
<td>Lower Intestine</td>
<td>7.73</td>
</tr>
<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 1.30
26.06 2.61

1. Values listed include a correction for a maximum of 0.1% indium in-114m radiocontamination at calibration.
3. Assumes 4.8 hour holding 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 0019-09050-42, is supplied with the following components:
1. A 10-mL OctreoScan Reaction Vial which contains a lyophilized mixture of:
   (i) 10 μg pentetreotide [N-2-dehydrotetraamine-N,N,N'-diacetic acid-N'-acyethyl-D-phenylalanine-L-histidine-L-tyrosine-L-cysteine-L-lysine-L-threonine]-cyctylic(2-7) disulphide, (also known as octreotide DTPA),
   (ii) 2.0 mg gentamic acid [2,5-dihydroxybenzoic acid],
   (iii) 4.9 mg thiosulphate, antihypertensive,
   (iv) 0.37 mg chloric acid, antihypertensive, and
   (v) 10.0 mg sodium.
2. 10 mL of Indium in-111 Chloride Sterile Solution, which contains 1.1 mCi of 111 MBq (3.0 mCi/L) indium in-111 chloride in 0.2 mL of sterile water at time of calibration. The vial also contains ferric chloride at a concentration of 3.5 mg/mL (feric ion, 1.2 μg/mL). The vials are sterile and nonpyrogenic. No bacteriostatic preservative is present.
3. A 10-mL vial of Indium in-111 Chloride Sterile Solution to the OctreoScan Reaction Vial, (2) a pressure sensitive label, and (3) a package insert.

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FROM LOS ANGELES TO ST. LOUIS:
THE YEAR IN REVIEW
With remarks by
Robert F. Carretta, MD, SNM President
Cynthia S. Wharton, CNMT, SNMSTS President
William J. Bertera, SNM Executive Director

FROM ST. LOUIS TO TORONTO:
THE YEAR AHEAD
With remarks by
Jonathan M. Links, PhD, SNM President-Elect
Kristin Waterstrom-Rich, CNMT, SNMSTS President-Elect

SNM: A GLOBAL SOCIETY
Highlights of the Society’s outreach activities to its international members and acknowledgement of attending international nuclear medicine society leaders.

RECOGNITION OF EXCELLENCE:
SNM 2000 AWARDS
• Presentation of the President’s Distinguished Service Awards to:
  Yasuhito Sasaki, MD, PhD, Director General, National Institute of Radiological Sciences, Tokyo, Japan, and former Chairman of the Board, Japanese Society of Nuclear Medicine.
  Terence M. Beven, MD, Director of Nuclear Medicine, Our Lady of the Lake R.M.C., Baton Rouge, Louisiana.
  Dr. and Mrs. William H. Blahd, founding members, Society of Nuclear Medicine Education & Research Foundation, Pacific Palisades, California.
  Robert W. Burt, MD, Director of Nuclear Medicine, Indiana University Hospital, Indianapolis, Indiana.
  Posthumously to Dov Front, MD, PhD, former Professor and Chairman of Nuclear Medicine, Rambam Medical Center, Haifa, Israel.
• Presentation of the 2000 Loevinger-Berman Award from the SNM MIRD Committee to Dandamudi V. Rao, PhD, University of Medicine & Dentistry, Newark, NJ.

INSTALLATION OF THE
2000-2001 SNM PRESIDENT
Installation of Jonathan M. Links, PhD, as President of the Society of Nuclear Medicine.
Positions Wanted

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Hawaii

Straub Clinic & Hospital is seeking a board certified/eligible physician to join its 170-physician multi-specialty group in Honolulu. 50% in nuclear medicine and 50% in diagnostic radiology. Duties include fluoroscopy, mammography, ultrasound, CT, and MRI. Comprehensive benefits include malpractice insurance, relocation allowance, and opportunity for partnership. Enjoy the superb lifestyle, excellent year-round climate, recreational and cultural diversity of Hawaii. Fax CV to: (808) 522-4038 or mail to: Ellen Sakai, Physician Recruitment Coordinator, Straub Clinic & Hospital, 888 South King Street, Honolulu, HI 96813; phone (800) 5-STRAUB.

Nuclear Pharmacy Manager

Candidates are sought for the position of Nuclear Pharmacy Manager within the University of Oklahoma Health Sciences Center College of Pharmacy. Successful candidates must be able to be licensed or be licensed as a pharmacist within the state of Oklahoma. Desired qualifications include board certification in Nuclear Pharmacy and three to five years of management experience in a nuclear pharmacy as well as interest in pharmaceutical education. Salary will be commensurate with education and experience. Resumes should be sent to: Carl K. Buckner, RPh, PhD, Dean, OUHSC College of Pharmacy, 1110 N. Stonewall, Room 133B, Oklahoma City, OK 73117 or e-mail to carl-buckner@ouhsc.edu. AA/EOE.

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 radiology a must. Capabilities in cross-sectional imaging and general radiology also required. Immediate availability. Please submit cover letter, CV and references to: C.R. Jarmolowski, MD, Department of Radiology, UPMC Shadyside Hospital, 5230 Centre Avenue, Pittsburgh, PA 15232.

Nuclear Medicine

Ochsner Clinic in New Orleans seeks a Board Certified Section Head for Nuclear Medicine to join our sixteen physician Department of Radiology. This section does approximately 550-600 exams per month. The candidate must also be qualified to teach in our free-standing residency program. Candidates should have completed an accredited training program. Fellowship training in PET is desirable. Ochsner is a physician owned and directed multi-specialty group practice, which includes more than 400 physicians in 27 locations across Southeast Louisiana. We offer an excellent salary, fringe benefit package and paid vacation. Interested physicians should send CV and contact: Edward I. Bluh, M.D., Chairman Department of Radiology, Ochsner Clinic, 1514 Jefferson Highway, New Orleans, LA 70121. Information: (504) 842-3470 or e-mail: ebluh@ochsner.org.

Postdoctoral Fellowship in PET/SPECT/MRI Imaging

Unique opportunity for postdoctoral training in functional brain imaging research. Emphasis on psychopharmacology and neuropsychiatric imaging. Special training in quantization techniques, research methods, and clinical applications. Didactic lectures, variety of projects, excellent mix of clinical and basic research. MD or PhD and clinical credentials required. Position can start as early as July 2000. Send applications to Dean F. Wong, MD, PhD, Johns Hopkins Medical Institutions, Radiology-JHOC Bldg. Room 3245, 601 N. Caroline Street, Baltimore, Maryland, 21287-0807. E-mail: dfwong@rad.jhu.edu. Fax: (410) 955-0696.

Board Certified Radiologist

Board Certified Radiologist with Nuclear Medicine expertise to join a 9-person group. The practice includes nuclear cardiology cases and is purchasing a hybrid PET scanner. Send CV to: David Yezersky, MD, Providence Saint Joseph Medical Center, 501 S. Buena Vista, Burbank, CA 91505. Phone: (818) 843-5111, ext. 7402. Fax: (818) 525-4953.

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**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

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**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 Lab does 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.

Located one hour north of Green Bay on scenic Lake Michigan, you can enjoy many outstanding recreational opportunities in Marinette. For consideration, please send resume or call:

**Recruiter, Bay Area Medical Center**

3100 Shore Drive

Marinette, WI 54443

Phone: (800) 789-2070, ext. 3115

Fax: (906) 845-1209

E-mail: bamschr@cybrzn.com
Chairman of Department of Nuclear Medicine

The Division of Radiology at the Cleveland Clinic Foundation is recruiting a Chairman of the Department of Nuclear Medicine as a full time staff position. The Cleveland Clinic provides research and clinical facilities, including a radiology residency program, PET scanning and a full complement of nuclear imaging capabilities. The Cleveland Clinic Foundation is a multi-specialty group practice and teaching hospital consisting of a main campus and affiliated regional hospitals within the Cleveland Clinic Health System. Candidates should be certified in Diagnostic Radiology and have Special Competency Certification in Nuclear Radiology. Administrative experience and a demonstrated commitment to scientific productivity are essential.

Interested candidates should send a cover letter and curriculum vitae to:

Gordon R. Bell, MD (Head of Search Committee)
Department of Orthopaedic Surgery-Neck A-41
Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, Ohio 44195

Call for Papers

The Journal of Nuclear Medicine (JNM)

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 on 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
Society of Nuclear Medicine
1850 Samuel Morse Drive
Reston, VA 20190-5316

Interested in Placing an Ad?

To place a classified advertisement in the JNM or JNMT please e-mail or fax the copy to the Advertising Department who will furnish an estimate. Hospital and company logos are accepted electronically for an additional charge. Line ads are $30 per line.

For display rates contact Stacey Silver at:
Phone: (703) 326-1183
Fax: (703) 708-9018

Biomedical Imaging Physicist/Biomedical Imaging Specialist

The biomedical detector research and development program within the Physics Division of the Thomas Jefferson National Accelerator Facility (Jefferson Lab) is seeking candidates for a medical physicist position. This program is focused on developing an array of nuclear medicine instruments for biomedical imaging that are related to cancer screening, diagnosis and treatment. Examples of the development efforts are:

- Dedicated gamma and positron breast and sentinel node imagers
- Dedicated adjunct gamma and positron spot imagers to assist digital mammography in breast biopsies
- Non-imaging and imaging beta/gamma probes for intra-operative use
- Small animal gamma and positron imagers

The successful candidate will assist the Detector Group in designing, testing and prototyping new medical instruments, as well as participate in pre-clinical and clinical assessments with Jefferson Lab’s biomedical partners.

Candidates should have direct experience in one or more of the following areas: nuclear imaging instrumentation as applied to medical or biological imaging, monte-carlo simulation, image reconstruction techniques and practical use of functional, metabolic or molecular in-vivo imaging technologies in patients or in small animals. Candidates with expertise primarily in nuclear medicine, SPECT and PET are strongly favored, but knowledge of CT and/or other imaging technologies important for cancer investigations is also desirable. Applicants should preferably have a PhD in Medical Physics or Biomedical Engineering or a related field, although Master’s level candidates may also be considered.

The successful candidate will be expected to assume a leading role in various medical instrumentation projects and initiate a vigorous program to obtain external funds for biomedical research. Applicants should send a curriculum vitae to:

Jefferson Lab
Attn: Employment Manager
12000 Jefferson Avenue, Newport News, VA 23606

Please specify position number PR2401 and job title when applying.

Visit our website at www.jlab.org/jobline.

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**Radiopharmacist/Nuclear Medicine Technologist**

Manages the Technical Services department to ensure that radiopharmaceutical products are compounded, dispensed, and administered appropriately in support of STR and future clinical research projects. Responsible for NeoRx pharmacy, leads team to establish and qualify radiopharmacy facilities; and ensures that all functions are in compliance with regulatory and safety requirements. Drafts sections of regulatory documents such as CMC section of an IND or NDA. Able to work under aggressive timelines, while maintaining effective relationships with internal and external personnel, such as contract manufacturers nuclear medicine facilities, and clinical departments. BS degree in chemistry discipline is required (MS preferred), with minimum of 5 years of experience with radiopharmaceuticals or R.Ph., BCNP.

Interested candidates are invited to forward their resume with a cover letter to: Human Resources Dept., NeoRx Corporation, 410 W. Harrison Street, Seattle, WA 98119; Email: jobs@neorx.com. An Equal Opportunity Employer

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**Nuclear Medicine Faculty Position**

The Department of Radiology at The University of Iowa College of Medicine has an opening for a Nuclear Medicine physician. This position is full-time, open rank and can be either tenure-track or non-tenure clinical track. One of the largest teaching hospitals in the country, the University of Iowa Hospitals and Clinics provides research and clinical facilities—a PET Center, state-of-the-art nuclear imaging equipment, and extensive image processing capabilities. Applicants must be certified in Nuclear Medicine and preferably in diagnostic radiology. PET expertise, administrative experience, and strong evidence of scientific productivity including extramurally funded research are desirable. Women and minority candidates are encouraged to apply.

**Send resume and cover letter to:**

Michael Graham, MD
Professor and Director
The University of Iowa
Department of Radiology, Division Nuclear Medicine
200 Hawkins Drive
Iowa City, IA 52242

The University of Iowa is an Affirmative Action/Equal Opportunity Employer

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**PET Applications & Education Specialist**

Alliance Imaging, Inc., the leading provider of MRI services in the US is seeking an experienced and professional PET technologist to join its Applications & Education Group. Primary job responsibilities involve both technical and sales support activities. The successful candidate will assist with the training of technologists and radiologists in the operation of PET and should have in-depth knowledge of PET products and be able to provide technical training. In addition, they should have significant clinical knowledge of PET in order to consult on scanning with physicians, department heads and technical personnel. Must be willing to travel. Please submit cover letter, resume and salary requirements to:

**Alliance Imaging, Inc.**
**Attention: Don Woodward**
**4912 Higbee Ave., NW**
**Canton, OH 44718**
**E-mail: dwoodward@allianceimaging.com**
When it comes to giving you the longest viewing area, no other camera comes close to matching the DST-XLi. Its 54.0cm (21.3 inch) FOV and unique long axis orientation deliver up to 40% more coverage from a single scan. That covers the entire torso for most common tomographic procedures – like bone metastasis or spinal evaluation – and is ideally suited for FDG coincidence imaging.

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For more information on the DST-XLi, visit our web site at http://www.smvnet.com or contact the DST-XLi representative nearest you.