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Inside Information.

Perfusion and function in one test: clinically relevant information.

Cardiolite® provides:

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- Enhanced diagnostic confidence with a high negative predictive value: A normal stress test correlates with a <1% annualized cardiac event rate\(^3-5\)
- Clinically relevant information in a range of situations—such as risk assessment, evaluation post-MI, and for chest pain management

For more information, contact DuPont Pharma at 1-800-362-2668 or www.radiopharm.com

There have been infrequent reports of signs and symptoms consistent with seizure and severe hypersensitivity after administration of Tc99m Sestamibi. Please see brief summary of prescribing information on adjacent page.
Cardiolite®
Kit for the preparation of Technetium Tc99m Sestamibi

F O R  D I A G N O S T I C  U S E

INDICATIONS AND USAGE: CARDIOLITE®, Kit for the preparation of Technetium Tc99m Sestamibi, is a myocardial perfusion agent that is indicated for detecting coronary artery disease by localizing myocardial ischemia (reversible defects) and infarction (non-reversible defects), in evaluating myocardial perfusion function in patient management decisions. CARDIOLITE® evaluation of myocardial ischemia can be accomplished with rest and cardiovascular stress techniques (e.g., exercise or pharmacologic stress in accordance with the pharmacologic stress agent's labeling).

It is usually not possible to determine the age of a myocardial infarction or to differentiate a recent myocardial infarction from ischemia.

CONTRAINdications:

None known.

WARNings:

In studying patients in whom cardiac disease is known or suspected, care should be taken to assure continuous monitoring and treatment in accordance with safe, accepted clinical procedures. Infrequently, death has occurred 4 to 24 hours after Tc99m Sestamibi use and is usually associated with exercise stress testing (see PRECAUTIONS).

Pharmacologic induction of cardiovascular stress may be associated with serious adverse events such as myocardial infarction, arrhythmia, hypotension, bronchoconstriction and cerebrovascular events. Caution should be exercised in pharmacologic stress testing after reconstitution; it should be used when indicated and in accordance with the pharmacologic stress agent's labeling.

PRECAUTIONS:

GENERAL

The contents of the vials are intended only for use in the preparation of Technetium Tc99m Sestamibi and are not to be administered directly to the patient without first undergoing the preparative procedure.

Radioactive drugs must be handled with care and appropriate safety measures should be used to minimize radiation exposure to clinical personnel. Also, care should be taken to minimize radiation exposure to the patient and related personnel.

Contents of the kit before preparation are not radioactive. However, after the Sodium Pertechnetate Tc99m Injection and Technetium Tc99m Sestamibi Injection are added, the kit must be maintained at room temperature until used.

The components of the kit are sterile and non-pyrogenic. It is essential to follow directions carefully and to adhere to strict aseptic procedures during preparation.

Technetium Tc99m labeling reactions depend on maintaining the stannous ion in the reduced state. Hence, Sodium Pertechnetate Tc99m Injection containing stannous ion must not be used.

Technetium Tc99m Sestamibi should not be used more than six hours after preparation.

Radiochemicals should be used only by physicians who are qualified by training and experience in the safe use and handling of radiotracers and whose experience and training have been approved by the appropriate government agency authorized to license the use of the radiotracers.

Stress testing should be performed only under the supervision of a qualified physician and in a laboratory equipped with appropriate resuscitation and support apparatus.

The most frequent exercise stress test endpoints, which resulted in termination of the test during controlled Tc99m Sestamibi studies (two-thirds were cardiac patients) were:

- Fatigue: 35%
- Dyspnea: 17%
- Chest Pain: 16%
- ST-depression: 76%
- Arrhythmias: 1%

Carcinogenesis, Mutagenesis, Impairment of Fertility

In comparison with most other diagnostic technetium labeled radiochemicals, the radiation dose to the ovaries (1.5 x 10^9 Bq of 99mTc - 1.2 x 10^6 Bq at 30 min) is very low. Minimal exposure (ALARA) is necessary in the preparation of children having cross-chromosome ability. (See Dosimetry subsection in DOSAGE AND ADMINISTRATION section.)

The active intermediate, [Cu(MIBI)]BF₄⁻, was evaluated for genotoxic potential in a battery of five tests. No genotoxic activity was observed in the Ames, CHO/K-FRT and sister chromatid exchange tests (all in vitro). At cytotoxic concentrations (2.5 x 10⁻⁶ M), an increase in cells with chromosome aberrations was observed in the in vitro human lymphocyte assay. [Cu(MIBI)]BF₄⁻ did not show genotoxic effects in the in vivo mouse micronucleus test at a dose which caused systemic and bone marrow toxicity (80 mg/kg > 600 x maximal human dose).

Pregnancy Category C

Animal reproduction and teratogenesis studies have not been conducted with Technetium Tc99m Sestamibi. It is unknown whether Technetium Tc99m Sestamibi can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. There have been no studies in pregnant women. Technetium Tc99m Sestamibi should be given to pregnant women only if clearly needed.

Nursing Mothers

Technetium Tc99m Pertechnetate is excreted in human milk during lactation. It is not known whether Technetium Tc99m Sestamibi is excreted in human milk. Therefore, formula feedings should be substituted for breast feedings.

Pediatric Use

Safety and effectiveness in children below the age of 18 have not been established.

ADVERSE REACTIONS:

During clinical trials, approximately 8% of patients experienced a transient paraesthesia or tachycardia (mild to severe) immediately after the injection of Technetium Tc99m Sestamibi. A few cases of transient headache, flushing, edema, injection site inflammation, dyspepsia, nausea, vomiting, pruritus, rash, urticaria, dry mouth, fever, dizziness, fatigue, dyspepsia, and hypotension have also been attributed to administration of the agent. Cases of angina, chest pain, and death have occurred (see WARNINGS and PRECAUTIONS). The following adverse events have been reported: signs and symptoms consistent with cocaine occurring shortly after administration of the agent; transient arthritis in a wrist; and severe hypersensitivity, which was characterized by dyspnea, hypotension, bradycardia, ashen and vomiting within two hours of administration of Technetium Tc99m Sestamibi.

DOSAGE AND ADMINISTRATION:

The dose administered should be the lowest required to provide an adequate study consistent with ALARA principles (see also PRECAUTIONS).

When used in the diagnosis of myocardial infarction, imaging should be completed within four hours after administration (see also CLINICAL PHARMACOLOGY).

The patient should be monitored with a suitable radioactivity calibration system immediately prior to patient administration. Radiochemical purity should be checked prior to patient administration. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

Store at 15-25°C before and after reconstitution.

RADIATION DOSIMETRY:

The radiation doses to organs and tissues of a average patient (70kg) per 111MBq (30mCi) of Technetium Tc99m Sestamibi injected intravenously are shown in Table 4.

Table 4. Radiation Absorbed Doses from Tc99m Sestamibi

<table>
<thead>
<tr>
<th>Source</th>
<th>2.0 hour void</th>
<th>4.0 hour void</th>
</tr>
</thead>
<tbody>
<tr>
<td>Organ</td>
<td>rads/mCi</td>
<td>rads/mCi</td>
</tr>
<tr>
<td>Brain</td>
<td>0.4</td>
<td>0.4</td>
</tr>
<tr>
<td>Lung</td>
<td>0.5</td>
<td>0.5</td>
</tr>
<tr>
<td>Heart</td>
<td>0.5</td>
<td>0.5</td>
</tr>
<tr>
<td>Liver</td>
<td>0.1</td>
<td>0.1</td>
</tr>
<tr>
<td>Kidney</td>
<td>0.1</td>
<td>0.1</td>
</tr>
<tr>
<td>Stomach</td>
<td>0.1</td>
<td>0.1</td>
</tr>
<tr>
<td>Urinary bladder</td>
<td>0.1</td>
<td>0.1</td>
</tr>
<tr>
<td>Total body</td>
<td>0.6</td>
<td>0.6</td>
</tr>
<tr>
<td>Organ</td>
<td>rads/mCi</td>
<td>rads/mCi</td>
</tr>
<tr>
<td>Brain</td>
<td>3.3</td>
<td>3.3</td>
</tr>
<tr>
<td>Lung</td>
<td>3.3</td>
<td>3.3</td>
</tr>
<tr>
<td>Heart</td>
<td>3.3</td>
<td>3.3</td>
</tr>
<tr>
<td>Liver</td>
<td>0.6</td>
<td>0.6</td>
</tr>
<tr>
<td>Kidney</td>
<td>0.6</td>
<td>0.6</td>
</tr>
<tr>
<td>Stomach</td>
<td>0.6</td>
<td>0.6</td>
</tr>
<tr>
<td>Urinary bladder</td>
<td>0.6</td>
<td>0.6</td>
</tr>
<tr>
<td>Total body</td>
<td>7.8</td>
<td>7.8</td>
</tr>
</tbody>
</table>

Radiopharmaceuticals

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REFERENCES:


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1998 CERTIFICATION EXAMINATION IN NUCLEAR CARDIOLOGY

DATE: October 25, 1998
TIME: 7:45 AM to 12:45 PM (Central Time)
LOCATION: Rosemont Convention Center, 5555 North River Road, Rosemont, Illinois

Deadline for Receipt of Applications: Early – May 22, 1998
Late – July 24, 1998

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**RAPID RETURN**
- <10-second half-life.
- Side effects usually resolve quickly and spontaneously.*

**WIDE OPEN**
- Consistently produces maximal vasodilation.
- Blood flow increases 3- to 4-fold over baseline.¹

**STRONG FINISH**
- Imaging comparable to exercise.
- Lower cost-per-case than dipyridamole.²
* Despite the short half-life, 10.6% of the side effects occurred not with the infusion of Adenoscan but several hours after infusion. Also, 8.4% of the side effects that began coincident with infusion persisted for up to 24 hours after infusion was completed. In many cases, it is not possible to know whether these late adverse events are the result of Adenoscan infusion.

Please see the brief summary of prescribing information on the following page.
BRIEF SUMMARY

Adenoscan®
adenosine

For Intravenous Infusion Only

DESCRIPTION
Adenosine is an endogenous nucleoside occurring in all cells of the body. It is chemically 6-amin-9-beta-D-ribofuranosyl-3'-H-purine. Adenosine is a white crystalline powder. It is soluble in water and practically insoluble in alcohol. Solubility increases by warming and lowering the pH of the solution.

Each Adenoscan® vial contains a sterile, non-pyrogenic solution of adenosine 3 mg/ml and sodium chloride 9 mg/ml, in Water for Injection, q.s. The pH of the solution is between 4.5 and 7.5.

INDICATIONS AND USAGE:
Intravenous Adenoscan® is indicated as an adjunct to thallium-201 myocardial perfusion scintigraphy in patients unable to exercise adequately. (See WARNINGS).

CONTRAINDICATIONS:
Intravenous Adenoscan® should not be administered to individuals with:
1. Second- or third-degree AV block (except in patients with a functioning artificial pacemaker).
2. Sinus node disease, such as sick sinus syndrome or symptomatic bradyarrhythmias (except in patients with a functioning artificial pacemaker).
3. Known or suspected bronchial asthma or bronchospastic lung disease (e.g., asthma).
4. Known hypersensitivity to adenosine.

WARNINGS:
Fetal Cardiac Arrest, Life Threatening Ventricular Arrhythmias, and Myocardial Infarction
Fetal cardiac arrest, sustained ventricular tachycardia, and nonfatal myocardial infarction have been reported concomitant with Adenoscan® infusion. Patients with unstable angina may be at greater risk.

Hypertension and Abdominal Aortic Model Block
Adenoscan® (adenosine) exerts a direct depressant effect on the SA and AV nodes and has the potential to cause first-, second-, or third-degree AV block. Approximately 5-50% of patients developing AV block with Adenoscan, including first-degree (2.9%), second-degree (3.6%) and third-degree (0.5%) heart block. All episodes of AV block were asymptomatic, transient, and did not require intervention. Adenoscan® can cause a transient decrease in blood pressure and/or an increase in heart rate in patients with high-grade AV block or sinus node dysfunction (except in patients with a functioning artificial pacemaker). Adenoscan should be discontinued in any patient who develops persistent or symptomatic high-grade AV block. Sinus pauses have been rarely observed with Adenoscan infusions.

Hypertension
Adenoscan® (adenosine) is a potent peripheral vasodilator and can cause significant hypertension. Patients with an intact baroreceptor reflex mechanism are able to maintain blood pressure and tissue perfusion in response to Adenoscan® by increasing heart rate and cardiac output. However, Adenoscan should be used with caution in patients with autonomic dysfunction, stenotic aortic valve disease, paroxysmal or paroxysmal arrhythmias, severe pulse deficits, and cardiovascular disease. Hypertension increases in systolic and diastolic pressure have been observed (as great as 140 mm Hg systolic in one case) concomitant with Adenoscan® infusion; most increases resolved spontaneously within several minutes, but in some cases, hypertension lasted for several hours.

Bronchoconstriction
Adenoscan® (adenosine) is a respiratory stimulant (probably through activation of cardiac bronchomotor receptors and intravascular injection in man has been shown to increase minute ventilation [VE] and reduce arterial PCO2, causing respiratory alkalosis. Approximately 20% of patients experience breathlessness (dyspnea) or a urge to breathe deeply with Adenoscan®. There are no reports of death or any other serious complications associated with Adenoscan® administration and it is considered safe in persons with asthma.

Adenoscan administered by inhalation has been reported to cause bronchoconstriction in asthmatics, presumably due to mast cell degranulation and histamine release. These effects have not been observed in normal subjects. Adenoscan® has been administered to a limited number of patients with asthma and in the absence of drug related symptoms or signs. Respiratory compromise has occurred during adenosine infusion in patients with obstructive pulmonary disease. Adenoscan® should be used with caution in obstructive lung disease not necessarily as asthma. (e.g., bronchospasm, bronchiolitis, etc.) and should be avoided in patients with bronchial obstruction or bronchospasm (e.g., asthma). Adenoscan should be discontinued in any patient who develops severe respiratory difficulties.

PRECAUTIONS
Drug Interactions
Intravenous Adenoscan® has been given with other cardiovascular drugs (such as beta adrenergic blocking agents, cardiac glycosides, and calcium channel blockers) without apparent adverse interactions, but effectiveness with these agents has not been systematically evaluated. Because of the potential for additive or synergistic depressant effects on the SA and AV nodes, however, Adenoscan® should be used with caution in the presence of these agents. The vasodilatory effects of Adenoscan® are inhibited by calcium channel blockers, such as verapamil (Diltiazem) and nifedipine (calcium channel blockers) may result in hypotension, such as decreases in arterial blood pressure, or increases in heart rate. Therefore, these agents should be used with caution in the presence of Adenoscan®.

Cardiogenic, Malignant Hypertension, Impairment of Fertility
Studies in animals have not been performed to evaluate the carcinogenic potential of Adenoscan® (adenosine). Adenosine in rats and mice at doses 400 and 800 mg/kg body weight, respectively, increased the incidence of malignant hyperplasia of the liver.

Adenoscan® has not been tested for effects on reproduction in any species. The safety and efficacy of Adenoscan® are based on the experience of adenosine, the active metabolite of Adenoscan®. The safety and efficacy of Adenoscan® in the presence of these agents have not been systematically evaluated. The safety and efficacy of Adenoscan® in the presence of these agents have not been systematically evaluated.

PRECAUTIONS
Animal reproduction studies have not been conducted with adenosine; nor have studies been performed in pregnant women. Because it is not known whether Adenoscan® can cause fetal harm when administered to pregnant women, Adenoscan® should be used during pregnancy only if clearly needed.

Pediatric Use
The safety and effectiveness of Adenoscan® in patients less than 18 years of age have not been established.

ADVERSE REACTIONS
The following reactions with an incidence of at least 1% were reported with intravenous Adenoscan® among 1,421 patients enrolled in controlled and uncontrolled U.S. clinical trials. Despite the short half life of adenosine, 10-20% of the side effects occurred not with the infusion of Adenoscan® but several minutes after the infusion terminated. Also, 8-10% of the side effects that last beyond the duration of the infusion persisted for up to 24 hours after the infusion was complete. In many cases, it is not possible to know whether these late adverse events are the result of Adenoscan® infusion.

Adverse Reactions in the following order of decreasing frequency:

Adverse Reactions:
- Flushing: 44%
- Gastronstestinal discomfort: 13%
- Short-term AV block: 3%
- Cheek flush: 44%
- Light-headedness/dizziness: 12%
- Hypertension: 2%
- Dizziness or urge to breathe deeply: 19%
- Upper extremity discomfort: 4%
- Hyperventilation: 2%
- Headache: 18%
- ST segment depression: 3%
- Nervousness: 1%
- Throat or neck discomfort: 15%
- First-degree AV block: 3%
- Arhythmias: 1%
- Adverse experiences of any severity reported in less than 1% of patients include:
- Bradycardia or (Bradycardia or tachycardia, bradycardia or tachycardia, or bradycardia or tachycardia)
- Cardiomegaly:
- Hemodynamic:
- Circulatory System: systemic perfusion; life-threatening ventricular arrhythmia, third-degree AV block; bradycardia; palpitation; sinus node disease (e.g., heart rate, bradycardia, T wave changes, hyperkalemia; systolic blood pressure > 200 mm Hg).
- Central Nervous System: dizziness; emotional instability; tremors.
- Gastrointestinal System: dyspepsia; weight loss; anorexia.
- Genito-Urinary System: urinary urgency; urgency.
- Respiratory System: cough.

Special Sensation: blurred vision; dry mouth; ear discomfort; metallic taste; nasal congestion; scotomata; tongue discomfort.

OVERDOSE:
The half-life of Adenoscan® is less than 10 seconds and side effects of Adenoscan® (adenosine) are usually resolved quickly when the infusion is discontinued, although delayed or persistent effects have been observed. Methylxanthines, such as caffeine and theophylline, are competitive antagonists of adenosine and their use has been associated with the occurrence of serious side effects. In contrast, U.S. clinical trials, theophylline (50-125 mg slow intravenous injection) was used to abort Adenoscan® side effects in less than 3% of patients.

DOSE AND ADMINISTRATION:
For Intravenous Infusion Only:
Adenoscan® should be given as a continuous peripheral intravenous infusion. The recommended intravenous dose for adults is 140 mcg/kg/min infused for 6 minutes (i.e., 100 mg/kg/min). The recommended dose of Adenoscan® for children is 1 mg/kg/min infused for 6 minutes (i.e., 100 mg/kg/min). The dosage should be adjusted to the patient's response to the infusion. The injection should be as close to the venous access as possible to prevent an inadvertent increase in the dose of Adenoscan®. There are no data on the safety or efficacy of alternative Adenoscan® infusion protocols.

The safety and efficacy of Adenoscan® administered by the intravenous route have not been established.

Note: Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration.

CAUTION:
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Guiding you to optimal intervention for neuroendocrine tumors

- Somatostatin receptor scintigraphy with OctreoScan can unequivocally detect and localize primary tumors and metastatic spread often missed by conventional imaging.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

The accepted standard for GEP tumors

An emerging choice for small cell lung cancer

OCTREOSCAN®
Kit for the Preparation of Indium In-111 Pentetreotide

SRS either unequivocally identified a primary tumor or clarified an equivocal lesion found on conventional imaging in 47% of patients with Zollinger-Ellison Syndrome undergoing initial evaluation. Of those with metastatic liver disease, SRS was the only localization method to determine the presence or extent of liver metastases in 12% of cases, or was the only method to establish additional metastases or metastases to the bone in 16% of cases.¹

Please see adjacent page for brief summary of prescribing information.
OCTREOSCANN® Kit for the Preparation of Indium In-111 Pentetreotide

BRIEF SUMMARY OF PRESCRIBING INFORMATION

DESCRIPTION
OctreoScan® is a kit for the preparation of indium In-111 pentetreotide, a diagnostic 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) ADMIXTURES OR INJECT INTO TPN INTRAVESSULAR ADMINISTRATION LINES. IN THESE SOLUTIONS, A COMPLEX GLUCOSYL OCTREOTIDE CONJUGATE MAY FORM.

The absence of toxicity with indium In-111 pentetreotide may be reduced in patients concurrently receiving therapeutic doses of pentetreotide. Consideration should be given to temporarily suspending octreotide 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 both 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 continue 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., senna or lactulose) before and after administration of indium In-111 pentetreotide (see Dosage and Administration section).
5. Indium In-111 pentetreotide should be tested for labeling yield of radioactivity prior to administration. The product must be used within six hours of preparation.
6. Components of the kit are sterile and nonpyrogenic. To maintain sterility, it is essential that directions are followed carefully. Aseptic technique must be used during the preparation and administration of indium In-111 pentetreotide.
7. Octreotide acetate and the natural somatostatin hormone may be associated with cholecystasis, presumably by altering fat absorption and possibly by decreasing motility of the gallbladder. A single dose of indium In-111 pentetreotide is not expected to cause cholecystasis.
8. As with any other radioactive material, appropriate shielding should be used to avoid unnecessary radiation exposure to the patient, occupational workers, and other persons.
9. Radiopharmaceuticals should be used only by physicians who are qualified by specific training in the safe use and handling of radiopharmaceuticals.

Carcinogenesis, Mutagenesis, Impairment of Fertility
Studies have not been performed with indium In-111 pentetreotide to evaluate carcinogenic potential or effects on fertility. Therefore, this product was not tested in an in vivo mouse micronucleus assay or an in vitro mammalian forward mutation assay. Evidence of mutagenicity was not found.

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

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

Pediatric Use
Safety and effectiveness in children have not been established.

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

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

DOSEAGE AND ADMINISTRATION
Before administration, a patient should be well hydrated. After administration, the patient must be encouraged to drink fluids liberally. Elimination of extra fluid intake will help reduce the radiation dose by flushing out unbound, labeled pentetreotide by glomerular filtration. It is also recommended that a mild laxative (e.g., senna 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-emptying process. In a patient with an insulinoma, bowel-emptying should be undertaken only after consultation with an endocrinologist.

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

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

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

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

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

Radiation Dosimetry
The estimated radiation dose to the average adult 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 Keimling, 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>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Kidneys</td>
<td>54.16</td>
<td>5.42</td>
</tr>
<tr>
<td>Liver</td>
<td>12.15</td>
<td>1.22</td>
</tr>
<tr>
<td>Spleen</td>
<td>73.86</td>
<td>7.39</td>
</tr>
<tr>
<td>Uterus</td>
<td>6.34</td>
<td>0.63</td>
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<tr>
<td>Ovary</td>
<td>4.89</td>
<td>0.49</td>
</tr>
<tr>
<td>Testes</td>
<td>2.90</td>
<td>0.29</td>
</tr>
<tr>
<td>Red Marrow</td>
<td>3.46</td>
<td>0.35</td>
</tr>
<tr>
<td>Bladder Wall</td>
<td>30.42</td>
<td>3.04</td>
</tr>
<tr>
<td>GI Tract</td>
<td>5.67</td>
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</tr>
<tr>
<td>Stomach Wall</td>
<td>4.78</td>
<td>0.48</td>
</tr>
<tr>
<td>Small Intestine</td>
<td>11.34</td>
<td>1.13</td>
</tr>
<tr>
<td>Upper Large Intestine</td>
<td>9.56</td>
<td>0.96</td>
</tr>
<tr>
<td>Lower Large Intestine</td>
<td>15.46</td>
<td>1.55</td>
</tr>
<tr>
<td>Adrenals</td>
<td>7.55</td>
<td>0.76</td>
</tr>
<tr>
<td>Thyroid</td>
<td>14.86</td>
<td>1.49</td>
</tr>
</tbody>
</table>

Effective Dose Equivalent: 13.03

1. Values listed include a correction for a maximum of 0.1% indium In-111m radiocount 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 0019-9050-40, is supplied with the following components:
1. A 10-ml OctreoScan Reaction Vial which contains a lyophilized mixture of:
   - 10 µg pentetreotide (N-[D-dehydrolysinorleucine-N,N,N,F-triaminocetic acid-H-acetyl-D-phenylalanine-L-histidine-N-acetyl-L-phenylalanine-D-tyrosine-L-Lysine-L-Leucine-L-Aspartic acid-L-Asparagine-L-Threonine-L-cystine (2-7) disulfide), (also known as octreoScan DTPA),
   - 2.2 mg gadolinium [D2-hydroxypropionic acid],
   - 4.8 mg magnesium chloride, and
   - 0.8 mg sodium chloride.

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

2. A 10-ml vial of Indium In-111 Chloride Solution, which contains 1.1 MBq (3.0 µCi/Ml) of indium In-111 chloride in 0.02 N HCl at time of calibration. The vials also contain ferum chloride at a concentration of 3.5 mg/L (ferum, 1.2 µg/mL). The vials contain sterile and nonpyrogenic. No bacteriostatic preservative is present.

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

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MI22701

Circle Reader Service No. 110
Did you know that ICD-9 diagnosis codes must be coded to the highest level of specificity or they will be rejected?

Are you aware of the new, revised and deleted CPT codes for nuclear medicine in 1998?

Did you know that a new hospital outpatient prospective payment system called APCs is scheduled for implementation in January 1999?

How should you modify a CPT code to get paid for 2 procedures on the same day? — and — When is it appropriate?

You will discover the answers to these questions and more at the SNM Reimbursement Seminar for Nuclear Medicine Procedures. This course will include.....

**TOPICS:**

- Coding Systems
- Resource-Based Relative Value Scale (RVUs)
- Hospital Billing
- Reimbursement Resources
- ICD-9 Coding
- Use of CPT
- Modifiers
- Special G Codes for PET Imaging
- Medicare’s Correct Coding Initiative
- Fraud and Abuse
- Remittance Advice (EOMBs)
- Claims Processing
- Medicare Appeals
- Practice Management
- Case Studies

**Location and Dates:**
Saturday, April 18, 1998
9:30 a.m. to 4:30 p.m.
Renaissance Madison Hotel
Seattle, Washington
Saturday, April 25, 1998
9:30 a.m. to 4:30 p.m.
Hotel Sofitel
Chicago, Illinois (near Chicago’s O’Hare airport)
Saturday, May 9, 1998
9:30 a.m. to 4:30 p.m.
Westin City Center
Washington, D.C.

**Speakers:**
Becky Caicciatore, CNMT, FSNMTS
Kenneth McKusick, MD, FACP, FACNP
Michael A. Wilson, MD, FACNP, FRACP

**Registration Fees:**
Registration Fees are $225.00 which includes the workbook, case studies, continental breakfast, lunch and an afternoon break. Contact Marie Davis at (703) 708-9000 x250 for additional information or a registration form.

**Accreditation Statement:**
The Society of Nuclear Medicine is accredited by the Accreditation Council for Continuing Medical Education and will offer a maximum of 6.0 hours in category 1 credits towards the AMA Physician Recognition Award. VOICE has approved 6.0 CEH for this session.

**Presentation Summary:**
This one day workshop will cover major procedural aspects of nuclear medicine services including proper code selection, claim submission and documentation. Nuclear medicine physicians and technologists, medical office managers, key billing and medical records personnel will learn to properly use the current CPT and ICD-9-CM manuals; use HCPCS II for effective coding and billing; understand third party payments; learn about the new G codes for PET imaging; be updated on the new editions of CPT and relevant Medicare changes; be fully cognizant and knowledgeable on the current Correct Coding Initiative and its implications of fraud and abuse; and review common procedures, fine tune coding skills and reimbursement algorithms.
Positions Available

Assistant Professor
Nuclear Medicine Division of UCSD Department of Radiology seeks an American Board of Nuclear Medicine BC/BE physician/radiologist for appointment in July, 1998. Responsibilities include clinical care, teaching and research at UCSD Hospital and the San Diego VA Healthcare System. PET fellowship or experience is preferred. Apply with CV, copies of 3 publications and 3 sealed letters of reference before May 10, 1998 to: David W. Yeung, MD, Chief, Nuclear Medicine Division, UCSD Medical Center, 200 W. Arbor Drive, San Diego, CA 92103-8758.

Nuclear Medicine ABNM Certified Physician
Mainly clinical position with some research and teaching opportunities. South Coast Nuclear Medicine, 229 W. Pueblo St., Santa Barbara, CA 93105.

PET Fellowship
The University of Pittsburgh is seeking a qualified individual for a fellowship position in state-of-the-art PET facility with a large neuroscience research program and active and growing clinical oncology service. Must be ABNM or ABR BC/BE. July start. The University of Pittsburgh is an affirmative action, equal opportunity employer. Interested individuals should send CV to: Carolyn Cidis Meltzer, MD, Medical Director, PET Facility, University of Pittsburgh Medical Center, B-938, 200 Lothrop Street, Pittsburgh, PA 15213-2582.

Position Wanted
Experienced ABNM-BC physician available for FT/PT. Practicing cardiac SPECT imaging for 13 years. For more information call Dr. Patel: (580) 357-8191.

CALL FOR TEACHING CASE STUDIES

The Society of Nuclear Medicine is embarking on a multi-year program to enhance the quality of nuclear medicine practice by providing a physician self-assessment program. The Society is calling upon our membership to submit case studies to be considered by the Practice Management Committee for inclusion in SNM PEP. Cases will be assessed by physicians with varied levels of nuclear medicine practice.

The Physician Evaluation Program (SNM PEP) will target full and part-time nuclear medicine physicians as well as referring physicians such as radiologists, cardiologists, oncologists, and endocrinologists. Participating physicians will dictate a report after review and interpretation of each patient case and receive educational feedback on areas of weakness for each case module scored. Phase one of the program will include five nuclear medicine modules covering cardiovascular, bone, lung, thyroid and scintimammography procedures.

We ask that each case contain 2-5 images which may be submitted as original film or original digital (preferred). In addition, you should submit the real patient history, patient scan time and any other pertinent information, correlative imaging if available, and a copy of the final report in a separate word processing file.

Upon acceptance of each complete case for utilization in an SNM PEP module you will receive a $100.00 honorarium. Unfortunately, no honoraria will be awarded for cases submitted but not chosen for utilization. The decision for acceptance by the Practice Management Committee will be final.

If your program is interested in learning more about this exciting opportunity to submit case studies, please contact Wendy Smith, Director of Health Care Policy, at the SNM Headquarters office at 703-708-9000, ext. 242.

Experienced ABNM certified physician with extensive experience in all aspects of diagnostic and therapeutic modalities including radiolabelled antibodies, I-131, Sr-89, etc. Also experienced in research, teaching, administration, and radiation safety, seeks challenging full-time position in a nuclear medicine practice. References available. Please respond by mail, fax or e-mail to: Society of Nuclear Medicine, Box #301-98, 1850 Samuel Morse Drive, Reston, VA 20190. Fax: 703-708-9018. E-mail: jmclean@snm.org.
Introducing PREP
Patient Related Educational Pamphlets

PREP (Patient Related Educational Pamphlets) on disk is now available for a low introductory price!

PREP provides patient information on diagnostic and therapeutic nuclear medicine procedures on a diskette in Microsoft WORD that you can reformat and customize to meet the needs of your institution. The PREP package includes: (1) a diskette of procedures (2) a printed reference page with all file names and (3) samples of how the PREP information can be used.

PREP will enable you to easily provide important information to your patients — promoting confidence and an understanding of their nuclear medicine procedure. Help to establish nuclear medicine as an integral part of patient care by giving referring physicians the PREP information.

PREP meets JCAHO standards for patient education and helps you adhere to accreditation compliance requirements.

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Signature: ____________________________________
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_____My check made out in the full amount and made payable to SNM is enclosed. (Mail form and check to: SNM, PREP, 1850 Samuel Morse Drive, Reston, VA 20190.)

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________________________________________________________
________________________________________________________

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