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Circle Reader Service No. 181
Spirit of Change

Siemens Nuclear Medicine Group
Siemens Medical Systems, Inc.
Nuclear Medicine Group
2501 North Barrington Road
Hoffman Estates, Illinois 60195-5203 U.S.A.
Telephone 847.304.7700
Spirit of Change

Siemens Nuclear Medicine Group
Siemens Medical Systems, Inc.
Nuclear Medicine Group
2901 North Barrington Road
Hoffman Estates, Illinois 60195-5203 U.S.A.
Telephone 847.304.7704
Confidence in motion

The goal of cardiac imaging is to obtain studies that allow you to accurately view the status of cardiac perfusion and function. And that’s where Cardiolite® comes through.

With *gated stress Cardiolite studies*, you simultaneously obtain stress perfusion and resting function (wall motion, wall thickening, and LVEF)—that’s more diagnostic information than perfusion alone, which can help you improve patient management. And, the higher photon energy (140 keV) reduces attenuation and improves image quality.

So remember, to enhance interpretive confidence and patient management, perform gated stress Cardiolite.

With gated stress Cardiolite studies you can...

- Acquire stress perfusion and resting function from one study
- Obtain function information for patients with diseases that coexist with CAD (eg, cardiomyopathies)
- Differentiate scar tissue from artifact
- Potentially reduce false-positive interpretations and the need for other costly and invasive procedures

Cardiolite®
Kit for the preparation of Technetium Tc99m Sestamibi

To reduce the uncertainty Cardiolite comes through

DU Pont Pharma
Radiopharmaceuticals

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

© 1996, DuPont Pharma
Brief Summary

Cardiolite®
Kit for the preparation of Technetium Tc99m Sestamibi

FOR DIAGNOSTIC USE

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 perfusion defects. It is useful in the evaluation of myocardial function and in the development of information for patient management decisions.

PRECAUTIONS:

GENERAL
The contents of the vial 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 drug must be handled with care and appropriate safety measures should be used to minimize radiation exposure to personnel. Also, care should be taken to minimize radiation exposure to the personnel consistent with proper patient management.

Contents of the kit before preparation are not radioactive. However, after the Sestamibi has been added to the kit Tc99m injection is added, adequate shielding of the final product must be maintained.

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 preparative procedures.

Technetium Tc99m labeling reactions involved depend on maintaining the stannous ion in the reduced state. Therefore, Sodium Pertechnetate Tc99m Injection containing oxidants should not be used.

Technetium Tc99m Sestamibi injections should not be administered to patients suffering from ST-depression or severe heart failure.

Radioisotopes should be used only by technicians who are qualified by training and experience in the safe handling and use of radionuclides and whose experience and training have been reviewed by the appropriate government agency authorized to license the use of radionuclides. 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 are noted as the result of test during controlled Tc99m Sestamibi studies (two-thirds were cardiac patients):

- Fatigue 20%
- Dyspnea 15%
- Chest Pain 16%
- ST-depression 7%
- Arrhythmia 1%

Cardiogenic, Mutagenesis, Impairment of Fertility
In comparison with most radioactive metabolites by radiopharmacologists, the radiation dose to the ovaries (1.5mrad/30mCi at rest, 1.2 mrad/30mCi at exercise) is high. Minimal exposure (ALARA) is necessary in women of childbearing capability. (See Dosimetry subsection in DOSAGE AND ADMINISTRATION section.)

The active intermediate, [Cu(MBII)BF4]−, was evaluated for genotoxic potential in a battery of five tests. No genotoxic activity was observed in the Ames, CHO/HTT and sister chromatid exchange tests (all n/a). At cytotoxic concentrations (20μg/ml), an increase in cells with chromosome aberrations was observed in the as mouse mouse lymphoma assay, [Cu(MBII)BF4]− did not induce genotoxic effects in the as mouse mouse lymphoma test at a dose which caused systemic and bone marrow toxicity (96h/kg, > 800 × maximal human dose).

Animal reproduction and teratogenicity studies have not been conducted with Technetium Tc99m Sestamibi. It is not known whether Technetium Tc99m Sestamibi causes fetal harm when administered to pregnant women or can affect reproductive capacity. There have been no studies in pregnant women. Technetium Tc99m Sestamibi should be given to a pregnant woman 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 substitutions should be based 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 pancreas and/or taste perversion (metallic or bitter taste) immediately after the injection of Technetium Tc99m Sestamibi. A few cases of transient headache, flushing, reddish skin reaction, eye irritation, conjunctivitis, or mild conjunctival symptoms have been reported. Several patients experienced an acute exacerbation of angina and chest pain, and a few patients have died (see WARNINGS and PRECAUTIONS).

The following toxic effects have been rarely reported: signs and symptoms associated with anxiety occurring shortly after administration of the agent; transient arthritis in a wrist joint; and severe hyperirritability, which was characterized by dyspnea, hypotension, bradycardia, asthma and vomiting within two hours after a second injection of Technetium Tc99m Sestamibi.

DOSEAGE AND ADMINISTRATION: The suggested dose range for I.V. administration in a single dose to be employed in the average patient (70kg) is:

| Tc99m Sestamibi | 370-1110MBq (10-30mCi) |

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 dose should be measured by 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.

Table 4. Radiation Absorbed Doses from Tc99m Sestamibi

<table>
<thead>
<tr>
<th>Organ</th>
<th>2.0 hour void</th>
<th>4.8 hour void</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>rad/ mCi</td>
<td>mGy/MBq</td>
</tr>
<tr>
<td>Organs of the Heart and Vessels</td>
<td>30mCi</td>
<td>1110MBq</td>
</tr>
<tr>
<td>Brain</td>
<td>0.2</td>
<td>2.0</td>
</tr>
<tr>
<td>Liver</td>
<td>2.0</td>
<td>20.0</td>
</tr>
<tr>
<td>Small Intestine</td>
<td>3.0</td>
<td>30.0</td>
</tr>
<tr>
<td>Upper Large Intestinal Wall</td>
<td>5.4</td>
<td>55.5</td>
</tr>
<tr>
<td>Lower Large Intestinal Wall</td>
<td>3.9</td>
<td>40.0</td>
</tr>
<tr>
<td>Stomach Wall</td>
<td>0.6</td>
<td>6.1</td>
</tr>
<tr>
<td>Heart Wall</td>
<td>0.5</td>
<td>5.1</td>
</tr>
<tr>
<td>Kidney</td>
<td>2.0</td>
<td>20.0</td>
</tr>
<tr>
<td>Liver</td>
<td>0.6</td>
<td>5.8</td>
</tr>
<tr>
<td>Lungs</td>
<td>0.3</td>
<td>2.8</td>
</tr>
<tr>
<td>Bone Surfaces</td>
<td>0.7</td>
<td>6.8</td>
</tr>
<tr>
<td>Thyroid</td>
<td>0.7</td>
<td>7.0</td>
</tr>
<tr>
<td>Ovaries</td>
<td>1.5</td>
<td>15.5</td>
</tr>
<tr>
<td>Testis</td>
<td>0.3</td>
<td>3.4</td>
</tr>
<tr>
<td>Red Marrow</td>
<td>0.5</td>
<td>5.1</td>
</tr>
<tr>
<td>Urinary Bladder Wall</td>
<td>2.0</td>
<td>20.0</td>
</tr>
<tr>
<td>Total Body</td>
<td>0.5</td>
<td>4.8</td>
</tr>
</tbody>
</table>

Table 5. Radiation Absorbed Doses from Tc99m Sestamibi

<table>
<thead>
<tr>
<th>Organ</th>
<th>2.0 hour void</th>
<th>4.8 hour void</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>rad/ mCi</td>
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</tr>
<tr>
<td>Organs of the Heart and Vessels</td>
<td>30mCi</td>
<td>1110MBq</td>
</tr>
<tr>
<td>Brain</td>
<td>0.2</td>
<td>2.0</td>
</tr>
<tr>
<td>Liver</td>
<td>2.8</td>
<td>28.9</td>
</tr>
<tr>
<td>Small Intestine</td>
<td>2.4</td>
<td>24.4</td>
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<tr>
<td>Upper Large Intestinal Wall</td>
<td>4.5</td>
<td>44.4</td>
</tr>
<tr>
<td>Lower Large Intestinal Wall</td>
<td>3.3</td>
<td>32.2</td>
</tr>
<tr>
<td>Stomach Wall</td>
<td>0.5</td>
<td>5.3</td>
</tr>
<tr>
<td>Heart Wall</td>
<td>0.5</td>
<td>5.6</td>
</tr>
<tr>
<td>Kidney</td>
<td>1.7</td>
<td>16.7</td>
</tr>
<tr>
<td>Liver</td>
<td>0.4</td>
<td>4.2</td>
</tr>
<tr>
<td>Lungs</td>
<td>0.3</td>
<td>2.6</td>
</tr>
<tr>
<td>Bone Surfaces</td>
<td>0.6</td>
<td>6.2</td>
</tr>
<tr>
<td>Thyroid</td>
<td>0.3</td>
<td>2.7</td>
</tr>
<tr>
<td>Ovaries</td>
<td>1.2</td>
<td>12.2</td>
</tr>
<tr>
<td>Testis</td>
<td>0.3</td>
<td>3.1</td>
</tr>
<tr>
<td>Red Marrow</td>
<td>0.5</td>
<td>4.6</td>
</tr>
<tr>
<td>Urinary Bladder Wall</td>
<td>1.5</td>
<td>15.5</td>
</tr>
<tr>
<td>Total Body</td>
<td>0.4</td>
<td>4.2</td>
</tr>
</tbody>
</table>

HOW SUPPLIED: Du Pont Radiochemicals’s CARDIOLITE®, Kit for the Preparation of Technetium Tc99m Sestamibi is supplied as a solid vial in kits of two (2), five (5) and thirty (30) vials, sterile and non-pyrogenic. Prior to reconstitution, the pH is between 5.3-5.9. The contents of the vials are lyophilized and stored under nitrogen. Store at 15-25°C before and after reconstitution. Technetium Tc99m Sestamibi contains no preservatives. Included in each two (2) vial kit are one (1) package insert, six (6) vial shield labels and six (6) radiation warning labels. Included in each five (5) vial kit are one (1) package insert, six (6) vial shield labels and six (6) radiation warning labels. Included in each thirty (30) vial kit are one (1) package insert, thirty (30) vial shield labels and thirty (30) radiation warning labels. The U.S. Nuclear Regulatory Commission has approved this reagent kit for distribution to persons licensed to use byproduct material pursuant to Sections 35.11 and 35.200 of Title 10 CFR Parts 35 and 35 which hold an equivalent license issued by an Agreement State, and, outside the United States, to persons authorized by the appropriate authority.

Marketed by
DuPont Radiochemicals
The DuPont Merck Pharmaceutical Co.
Wilmington, Delaware 1989, U.S.A.
Billerica, Massachusetts, USA 01822
For ordering Tel. Toll Free: 800-225-3572
For wholesale: 609-362-8969
(For Massachusetts and International, call 508-687-9351)

513121-0296 1/96 Printed in U.S.A.
A sign of things to come in cardiac imaging
Maximal Vasodilation
for patients unable to exercise adequately

Imaging comparable to maximal exercise

- Interpretable images obtained in 98.7% of patients
- Maximal coronary hyperemia achieved in 2-3 minutes
- No supplemental exercise necessary

Stress Redistribution

Rapid onset, short duration

- <10-second half-life minimizes post-infusion monitoring time
- Side effects usually resolve quickly

ADENOSCAN®
adenosine

Please see brief summary of prescribing information on adjacent page for warnings, precautions and contraindications.

BRIEF SUMMARY

For Intravenous Infusion Only

**DESCRIPTION**

Adenosine is an endogenous nucleoside occurring in all cells of the body. It is chemically 8-endo-9-ribofuranosyl-9H-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® 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 Adenosine is indicated as an adjunct to thallium-201 myocardial perfusion scintigraphy in patients unable to exercise adequately. (See WARNINGS.)

**CONTRAINDICATIONS**

Intravenous Adenosine (adenosine) should not be administered to individuals with:

1. Second- or third-degree AV block (except in patients with a functioning artificial pacemaker).
2. Severe bradycardia (e.g., sick sinus syndrome or symptomatic bradycardia).
3. Known or suspected bronchoconstrictive 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 (requiring resuscitation), and nonfatal myocardial infarction have been reported coincident with Adenoscan infusion. Patients with unstable angina may be at greater risk.

Scoliosis and/or Ventricular Ventrilolateral Block

Adenosine (adenosine) events a direct depressant effect on the SA and AV nodes and has the potential to cause first-, second- or third-degree AV block, or atrioventricular block. Approximately 5% of patients developing AV block with Adenoscan, including first-degree (2:1P:2R), second-degree (2:1P or 3:1P:2R) and third-degree (2:1P) heart blocks. All episodes of AV block have been asymptomatic, transient, and did not require intervention. Adenoscan can cause atrioventricular block. Adenosine should be used with caution in patients with pre-existing first-degree AV block or atrioventricular block and should be avoided in patients with high-grade AV block or atrioventricular dyssynchrony (except in patients with a functioning artificial pacemaker). Adenoscan should be discontinued in any patient who develops persistent or symptomatic high-grade AV block. Since pause has been rarely observed with Adenoscan administration.

Hypotension

Adenosine (adenosine) is a potent peripheral vasodilator and can cause significant hypotension. 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. Hypotension should be treated with caution in patients with autonomic dysfunction, atrial or ventricular heart disease, peripheral or pulmonary effusions, aortic or mitral valve disease with concomitant insufficiency, or uncorrected hypovolemia, due to the risk of hypotensive complications in these patients. Adenoscan should not be administered to any patient who develops persistent or symptomatic hypotension.

Hypertension

Increases in systolic and diastolic pressures have been observed in individuals (e.g., 140 mm Hg systolic in one case) coincident with Adenoscan infusion. Mild increases resolved spontaneously within several minutes. In some cases, hypertension lasted for several hours.

Breschothrombosis

Adenosine (adenosine) is a respiratory stimulant (probably through activation of carotid body chemoreceptors) and intravenous administration in man has been shown to increase minute ventilation (TVs) and reduce arterial PO2 (pulmonary alveolar) approximately 29% of patients experiencing an acute respiratory depression or an urge to breathe deeply with Adenoscan. These respiratory complaints are transient and only rarely require intervention.

Adenosine administered by inhalation has been reported to cause bronchoconstriction in asthmatic patients, presumably due to the release of histamine. These effects have not been observed in normal subjects. Adenoscan has been administered to a limited number of patients with chronic obstructive pulmonary disease. Adenoscan may have occurred during adenosine infusion in patients with obstructive pulmonary disease. Adenoscan should be used with caution in patients with obstructive lung disease not associated with acute exacerbation of e.g., asthma, bronchitis) and should be avoided in patients with bronchoconstriction or bronchoospasm (e.g., asthma). Adenoscan should be discontinued in any patient who develops severe respiratory difficulties.

**PRECAUTIONS**

**Drug Interactions**

Intravenous Adenosine (adenosine) may have given with other cardiovascular drugs (such as beta adrenergic blocking agents, cardiac glycosides, and calcium channel blockers) without apparent adverse interactions, but its effectiveness with these agents has not been systematically evaluated. Because of the potential for additive or synergistic depressive effects on the SA and AV nodes, however, Adenoscan should be used with caution in concomitant treatment with these agents. The vasodepressant effects of Adenoscan may be enhanced by adrenergic receptor antagonists, such as atenolol (e.g., atenolol and theophyline). The safety and efficacy of Adenoscan in the presence of these agents has not been systematically evaluated. The use of Adenoscan in the presence of hypoglycemia has not been systematically evaluated. Whenever possible, drugs that might inhibit or augment the effects of adenosine should be withheld for at least five half-lives prior to the use of Adenoscan.

Carbohydrate Metabolism, Impairment of Fertility

Studies in animals have not been performed to evaluate the carcinogenic potential of Adenoscan (adenosine). Adenosine was negative for general toxicity and fertility (Sereid and Mammalian Microsome Assay). Adenoscan, however, like other nucleotides at millimolar concentrations present for several doubling times of cells in culture, is shown to produce a variety of cellular alterations. In rats and mice, adenosine administered intraperitoneally once a day for five days at 50, 100, and 150 mg/kg (10-30-fold) and 15-15 (most times human dosage on a mg/kg basis) caused decreased spermatogenesis and increased numbers of abnormal spermatids, an indication of the ability of adenosine to produce chromosomal damage.

**Pregnancy Category C**

Animal reproduction studies have not been conducted with adenosine. No studies have 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 observed with intravenous Adenoscan among 1421 patients enrolled in controlled and uncontrolled U.S. clinical trials. Despite the short half-life of adenosine, 10% of the side effects occurred not with the infusion of Adenoscan but rather with the infusion intervals. Therefore, the incidence presented above refers to the infusions followed by the intervals presented. In any case, it is not possible to say whether these late adverse events are the result of Adenoscan infusion.

Flushing 44%
Gastrointestinal discomfort 13%
Second-degree AV block 9%
Chills/decreased 42%
Lightheadedness/vertigo 12%
Nausea 9%
Dyspnea or urge to breathe deeply 29%
Upper extremity discomfort 4%
Hypotension 29%
Headache 9%
27 segment depression 3%
Hypokalemia 29%
Throat, neck or jaw discomfort 15%
First-degree AV block 3%
Arthralgias 1%
Adverse experiences of any severity reported in less than 1% of patients include:

Bronchospasm, cough or Bronchial reflex; dyspnea or bronchospasm: weakness.

Cardiovascular System: nonfatal myocardial infarction, life-threatening ventricular arrhythmias; third-degree AV block, bradycardia, palpitation; atrioventricular block, sinus pauses, widening, + wave changes, hypotension (systolic blood pressure > 200 mm Hg).

Central nervous system: drowsiness, emotional instability, tremors.

Gastrointestinal System: vomiting, nausea.

Respiratory System: cough.

Special Senses: blurred vision; dry mouth; ear discomfort; metallic taste; nasal congestion; otosine; tongue discomfort.

OVERDOSE:

The half-life of Adenosine is less than 10 seconds and side effects of Adenoscan (adenosine) when they usually occur quickly when the infusion of adenosine is discontinued, although delayed or persistent effects have been observed. Methylenidrines, such as caffeine and theophyline, are competitive adenosine receptor antagonists, and theophyline has been used to effectively terminate persistent side effects. In studies of U.S. clinical trials, theophyline (50-125 mg) given intravenously over 30 minutes was used to avoid adenosine effects in less than 2% of patients.

**DOSAGE AND ADMINISTRATION**

For intravenous infusion only.

Adenoscan should be given as a continuous peripheral intravenous infusion. The required dose of adenosine for adults is 140 mcg/kg/hour infused for at least 6 or 60 mg/kg (total dose of 0.64 mg/kg). The required dose of thallium-201 should be injected at the midpoint of the Adenoscan infusion (i.e., after the first three minutes of Adenoscan infusion). Adenoscan is compatible with Adenoscan and may be injected simultaneously into the same venous access. The injection should be as close to the venous access as possible to prevent an inadvertent increase in the dose of Adenoscan (the contents of the N tubing being administered). There are no data on the safety or efficacy of alternative adenosine infusion protocols. The desired activity of Adenoscan administered by the intravenous route has not been established.

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

**CAUTIONS**

Federal law prohibits dispensing without prescription.

Fujisawa USA, Inc.
Deerfield, IL 60015
Under license from Mecho Research, Inc.
Research Triangle Park, NC 27709

Circle Reader Service No. 50
Technetium Tc99m Tetrofosmin For Injection

so clear...

so flexible!

See brief summary of prescribing information on the following page.
**Myoview™**

**Kit for the Preparation of Technetium Tc99m Tetrofosmin for injection**

Diagnostic radiopharmaceutical For intravenous use only

**Code N116A**

**DESCRIPTION**

The Medi-Physics Myoview™ kit is supplied as a pack of five vials for use in the preparation of a technetium Tc99m tetrofosmin injection to be used for scintigraphic delineation of regions of reversible myocardial ischemia in the presence or absence of infarcted myocardium. Each vial contains a pre-dispersed, sterile, non-pyrogenic, lyophilized mixture of 0.23 mg tetrofosmin [6,8-bis-(2-ethoxyethyl)-3,12-dioxa-6,9-diphospha-tetradecane], 30 μg stannous chloride dihydrate [minimum stannous tin 5.0 μg; maximum total stannous and stannic tin 15.8 μg], 0.32 mg disodium phosphosulfocitrate and 1.0 mg sodium D-glucuronate, and 1.8 mg sodium hydrogen carbonate. The lyophilized powder is sealed under a nitrogen atmosphere with a rubber closure. The product contains no antimicrobial preservative.

**Caution:** Federal (USA) law prohibits dispensing without a prescription

**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 atypical chest pain who had a reason for exercise stress testing were studied in two open-label, multi-center, clinical trials of technetium tetrofosmin (study 1 and study 2). 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 of 5.1 days (1-14 days before or 2-14 days after Myoview). For Myoview imaging, each patient received 185-296 MBq (5-6 mCi) Tc99m tetrofosmin at peak exercise and 555-688 MBq (15-24 mCi) Tc99m tetrofosmin at rest approximately 4 hours later. For thallium-201 imaging, patients received thallium-201 55.5-74 MBq (1.5-2.0 mCi) 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 permit 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.

Radioisopharmaceuticals 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.

**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.

**Cardiogenesis, Mutagenesis, Impairment of Fertility**

Studies have not been conducted to evaluate carcinogenic potential or effects on fertility. Tetrofosmin phosphosulfocitrate was not 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.

**Pediatric Use**

Safety and effectiveness in pediatric patients have not been established.

**ADVERSE REACTIONS**

Adverse events were evaluated in clinical trials of 764 adults (511 men and 253 women) with a mean age of 58.7 years (range 24-94 years). The subjects received a mean dose of 7.67 MBq on the first injection and 22.4 MBq 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 5764 (less than 1%) of patients after Myoview injection.

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

- **Cardiovascular:** angina, hypertension, Torsade de Points (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 significant 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 Table 1. The values are listed in descending order as rad/MCi and yGy/MBq and assume urinary bladder emptying at 3.5 hours.

<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>0.180</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>0.151</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>0.103</td>
</tr>
<tr>
<td>Kidney</td>
<td>0.029</td>
<td>0.046</td>
</tr>
<tr>
<td>Salivary glands</td>
<td>0.030</td>
<td>0.043</td>
</tr>
<tr>
<td>Ovaries</td>
<td>0.029</td>
<td>0.035</td>
</tr>
<tr>
<td>Urnus</td>
<td>0.027</td>
<td>0.031</td>
</tr>
<tr>
<td>Bone sarce</td>
<td>0.023</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>0.016</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>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>0.011</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>0.006</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). Special of Nuclear Medicine, 1975. Effective dose equivalents (EDE) were calculated in accordance with ICRP 53 (Ann. ICRP 18 (1-4), 1988) and gave values of 8.61 x 10^-18 mSV/MBq and 1.12 x 10^-18 mSV/MBq after exercise and rest respectively.

Manufactured by Amersham International plc - Amersham, United Kingdom

Patent No. 5,045,302 (r)

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CERTIFICATION COUNCIL OF NUCLEAR CARDIOLOGY

1996 CERTIFICATION EXAMINATION IN NUCLEAR CARDIOLOGY

DATE: Tuesday, September 10, 1996
TIME: 8:00 AM to 12 Noon (Eastern Time)
LOCATION: Grand Hyatt Washington Hotel, 1000 H Street, NW, Washington, DC

Deadline for Receipt of Applications: July 16, 1996

You are urged to write as soon as possible for the Candidate Bulletin and application form to:

Certification Council of Nuclear Cardiology
7111 Pyle Road
Bethesda, MD 20817
Phone or FAX: 301-320-0399
Abdominal MRI indicated evidence of recurrent disease...

Abdominal MRI indicating evidence of hepatic tumor.
Patient History

This middle-aged male underwent resection of a pancreatic carcinoid tumor four years ago. Subsequent 3 and 4 year CT scans presented evidence of recurrent disease. The patient was referred for OctreoScan imaging.

OctreoScan Scintigraphy

Five hepatic tumors and two periaortic nodal lesions were clearly visible on the whole-body planar images. OctreoScan imaging enabled differentiation between a non-receptor-expressing cavernous hemangioma and receptor-positive carcinoid metastases.

Clinical Course

Correlative MRI indicated disease, but some lesions would likely have been missed without the benefit of OctreoScan scintigraphy. The patient underwent surgery to freeze all five hepatic lesions identified by OctreoScan. Follow-up MRI and OctreoScan studies were planned to assess post-operative status.

Decisive Clinical Information

In patients who have a known or suspected neuroendocrine tumor, OctreoScan imaging often can be the difference between cautious uncertainty and decisive clinical intervention. Contact your nuclear medicine specialist for more information.

OctreoScan whole-body images showing five hepatic lesions and two periaortic lesions.

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 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) ADJUVANT OR INJECT INTO TPN INTRAVENOUS ADMINISTRATION LINES. IN THESE SOLUTIONS, A COMPLEX GLYCOSYL OCTREOTIDE CONJUGATE MAY FORM.

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

PRECAUTIONS
General
1. Therapy with octreotide acetate can produce severe hypoglycemia in patients with insulinomas. Since pentetreotide is an analog of octreotide, an intravenous line is recommended in any patient suspected of having an insulinoma. An intravenous solution containing glucose should be administered just before and during administration of indium In-111 pentetreotide.
2. The contents of the two vials supplied with the kit are intended only for use in the preparation of indium In-111 pentetreotide and are NOT to be administered separately to the patient.
3. Since indium In-111 pentetreotide is eliminated primarily by renal excretion, use in patients with impaired renal function should be carefully considered.
4. To help reduce the radiation dose to the thyroid, kidneys, bladder, and other target organs, patients should be well hydrated before the administration of indium In-111 pentetreotide. They should increase fluid intake and void frequently for one day after administration of 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 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.

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

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

Nursing Mothers
It is not known whether the 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 patients: dizziness, drowsiness, flush, headache, hypotension, changes in liver enzymes, joint pain, nausea, sweating, and weakness. These adverse effects were transient. Also in clinical trials, there was one reported case of bradycardia and one case of decreased hematocrit and hemoglobin.

Pentetreotide is derived from octreotide which is used as a therapeutic agent to control symptoms from certain tumors. The usual dose for indium In-111 pentetreotide is approximately 5 to 20 times less than for octreotide and is subtherapeutic. The following adverse reactions have been associated with octreotide in 3% to 10% of patients: nausea, injection site pain, diarrhea, abdominal pain/discomfort, loose stools, and vomiting. Hyperperspiration 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. Adequate fluid intake is necessary during this period as a support both to renal elimination and the bowel-cleansing process. In a patient with an insusceptible, bowel-cleansing should be undertaken only after consultation with an endocrinologist.

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

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

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

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

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

Radiation Dose
do not administer OctreoScan in TPN solutions or through the same intravenous line.

Radiation Dose
do not administer OctreoScan in TPN solutions or through the same intravenous line.

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>Urine</td>
<td>10.0</td>
</tr>
<tr>
<td>Bladder</td>
<td>30.42</td>
</tr>
</tbody>
</table>

1. Values listed include a correction for a maximum of 0.1% indium In-114m 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 0019-0950-01, is supplied with the following components:
1. A 10-ml OctreoScan Reaction Vial which contains a lyophilized mixture of:
   - (i) 10 μg pentetreotide [N-(dehydroxyphenylalanine-γ-NY-NH₂, l-epacetyl-l-D-phenylalanine-γ-NY-NH₂, l-epacetyl-l-tyrosine]-cyclodeca-2,4-diene-(2-γ)-dualyl (also known as octreotide DTPA).
   - (ii) 2.0 mg gentamic acid [2.5-dihydroxy-2-aminomethylpentanoic acid].
   - (iii) 4.0 mg thallium citrate, anhydrous.
   - (iv) 0.37 mg clindamycin phosphate, anhydrous.
   - (v) 1.0 mg sodium bicarbonate.
2. A 10-ml vial of Indium In-111 Chloride Sterile Solution, which contains 1.1 ml of 111 MBq (3.0 mCi) of Indium In-111 chloride in 0.02 N HCl at time of calibration. The vial also contains ferric chloride at a concentration of 3.5 μg/ml (ferri ion, 1.5 μg/ml). The vial contents are sterile and nonpyrogenic. No bacteriostatic preservative is present.

In addition, the kit also contains the following items: (1) a 25 G x 6½ inch needle (BD, Monoject) used to transfer Indium In-111 Chloride Sterile Solution to the OctreoScan Reaction Vial, (2) a pressure sensitive label, and (3) a package insert.

Marcinik Medical, Inc.,
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Unexpected opening in Nuclear Medicine fellowship program beginning July 1996. One or two year program leading to board eligibility. Full range of education including PET, radiopharmaceutical therapy, pediatrics and opportunities to do research. Applicants should have completed two years of an approved residency program. Apply: David E. Kuhl, MD, Division of Nuclear Medicine, University of Michigan Medical Center, 1500 E. Medical Center Drive, Ann Arbor, MI 48109-0028. Phone: 313-936-5388, Fax: 313-936-8182.

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Prepare, measure, administer radiopharmaceuticals in diagnostic and therapeutic studies, utilizing a variety of equipment and following prescribed procedures; prepare stock solutions of radiopharmaceutical materials, calculate doses and administer doses. Calibrate equipment. Perform diagnostic studies on patients using scanners or scintillation cameras to detect radiation emitted and to produce image of organ on photographic film. Measure radioactivity, using Geiger counters, scales and scintillation detectors. Administer therapeutic doses of radiopharmaceuticals under direction of physician. Salary $11.56 per hour. Forward resumes to Job Service of Florida, 2810 Sharrer Road, Suite 30-B, Tallahassee, Florida 32312. Ref. Job Order No. FL-1380064.

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This is a 2 year research fellowship position in the Section of Nuclear Medicine at Mayo Clinic, with a primary focus on the development and clinical validation of quantitative techniques for tomographic imaging of the heart. Mayo Clinic has one of the largest nuclear medicine departments in the US, with over 20 gamma cameras and a large integrated computer network. Applicants should have a doctorate degree in physics. Preference will be given to candidates with previous experience in SPECT imaging. Please forward CV to Michael K. O'Connor, Ph.D., Section of Nuclear Medicine, Mayo Clinic, Rochester, MN 55905, fax (507) 266-4461.

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Application forms and further particulars are available from Personnel Services, University of Aberdeen, Regent Walk, Aberdeen AB9 1FX, telephone (01224) 272727 quoting reference number FBS006AX. A 24-hour answering service is in operation.

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Applicants should submit letters, C.V., and a brief description of current and proposed research immediately to Trey Sunderland, MD, Chief, Section on Geriatric Psychiatry, NIMH, 9000 Rockville Pike, Bldg 10, Rm. 3D41, Bethesda, MD 20892; Fax: 301-402-0188.

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Send curriculum vitae and a statement of interest to:

Stanley J. Goldsmith, M.D.
Director, Division of Nuclear Medicine, 1300 York Avenue, New York, NY 10021.
FAX: 212-746-8573.
EEO/AA/M/F/D/N.

To place a classified advertisement, call:
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**Volume 4:** "Quantitative Cholescintigraphy," Gerbail Krishnamurthy, MD

**Volume 5:** "Combined Myocardial Perfusion/Function Imaging," Mark D. Wittry, MD

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