Designed like no other radioaerosol system...anywhere.

1 Safety. Any time you’re dealing with radioactive material, safety comes first. That’s why the Aero/Vent shield gives us the highest safety standard of any radioaerosol inhalation system available.

2 Portability. The Aero/Vent weighs only 12 pounds. That, combined with its one-handle design, makes the Aero/Vent a breeze to transport.

3 Optional cabinet. A popular accessory for the Aero/Vent is a mobile cabinet which contains an adjustable arm to position the shield (for both upright and supine positions), a leaded decay bin and an oxygen tank holder.

4 The Safety/Shield. Only the Aero/Vent features the SAFETY/SHIELD™ Mouthpiece—which incorporates a cover that seals the mouthpiece before and after patient use. This minimizes potential radiation spread and contamination for both the patient and the technologist.

5 Easy patient breathing. The Aero/Vent’s unique “no valve” design allows virtually unrestricted patient breathing.

6 Efficiency. The Aero/Vent’s high efficiency rate reduces breathing time for most patients to 2-5 minutes.

7 Particle size. Particle size of .3 micron (MMAD) produces images of unsurpassed quality.

8 Customer Support. The Aero/Vent is manufactured by Medi/Nuclear, a company dedicated to producing first-class radioaerosol systems. If you ever have any questions or comments, just give us a call.

The Aero/Vent is available through:
MPI/Amersham Healthcare (800-633-4123)
Syncor International (800-999-9098)
Medi/Nuclear Corporation (818-960-9822)
The All-New Digital PRISM™ XP Series Systems

Picker's all-new PRISM XP Series systems are ready to meet your healthcare challenges.

• SUPERIOR DIGITAL IMAGE QUALITY
  Our new PRISM XP systems feature microprocessor-controlled detector and PMT electronics that not only provide superior image quality, but also ensure extended image stability and reliability.

• ADVANCED CLINICAL APPLICATIONS
  The new, compact, and ultra-fast Odyssey™ VP computer is based on the leading RISC workstation technology and application software. Combined with our window-based, graphical user interface, complex procedures are only a mouse click away.

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  Our Telapath Resource Hub is just a phone call away and ready to provide you with the right technical assistance to keep your department at peak performance. One phone call to our Applications and Service Support Specialists helps you solve problems fast. We can even log on to your system remotely by phone to evaluate images and run diagnostic programs to pinpoint potential problems. All this to save you time.

For the complete story on the new PRISM XP Series, call 1-800-323-0550.
"ARE MY Sr-89 CALIBRATIONS CORRECT?" — is the Question

**WITH CAPINTEC — IS THE ANSWER**

Eliminate the guesswork and potential errors from your Sr-89 and P-32 beta measurements

Capintec's Newest Member in our Excellent Family of Dose Calibrators **beta C** offers:

- Fast Reading of Pure β's used in the control of Bone Pain
- Geometry independence using Syringes or Vials
- Easy and Accurate Beta Counting
- Automatic Impurity Identification
- Non-Destructive Counting
- Highest Accuracy through the use of a NaI crystal detector

The Capintec **beta C** adds a new dimension to radionuclide measurement. Engineered specifically for pure beta emitters such as P-32 and Sr-89, the **beta C** takes the guesswork and errors out of your beta assays.

Through the creative use of a special NaI crystal detector, geometry and gamma contamination problems are eliminated. The **beta C** allows dose measurement in vials and syringes with equal precision and ease.

The **beta C** accepts calibration factors for over 20 radionuclides plus the ability to store source data with automatic decay correction, making daily tests effortless.

With an optional printer, hard copy print-outs of all information is displayed on screen including an energy histogram, if required. The **beta C** with printer provides patient records and daily test information to satisfy existing and future regulatory requirements.

**AS A LEADER IN ENERGY MEASUREMENT DEVICES, CAPINTEC'S GOAL IS TO MEET YOUR DEMANDS WITH THE LATEST, HIGHEST QUALITY, COST-EFFECTIVE SOLUTIONS**...
XPert™
Make an expert decision

Elscint
**XPert Aided Diagnosis**

A built-in knowledge-base and advanced algorithms empower XPert to analyze data intelligently, infusing its processing modules with NM technical expertise. Propelled by superscalar micro-computing power, XPert helps you expand the frontiers of nuclear imaging.

XPert's Toolbox includes interactive graphical tools for high precision lesion delineation. And smart image structure interpretation totally automates SPECT reconstruction, homing in on target tissues, without operator intervention.

**An XPert Display of Power**

A multi-processor array of Intel Pentium and RISC number crunchers energizes XPert with 122 Mflops / 150 MIPS for 30 msec/slice SPECT reconstruction speed. A 30 Mpixel/sec graphic engine with 1280x1024 display reveals lesions with remarkable sharpness. Advanced clinical macro-programming expands XPert's diagnostic power with the vast repertoire of CLIP programs, developed by thousands of Apex users over the last decade.

**XPert Link, Universal Connectivity**

XPert is a great communicator. Reaching out beyond its total link with Elscint imagers, it networks equally well with others. And XPert provides a transparent digital connection to fine-resolution laser multi-imagers and color printers. Superior PACS capabilities yield optimal equipment-use, boosting departmental productivity and cutting equipment costs.

---

**XPert™**

Knowledge is power... the power of the expert.

---

Elscint/U.S.A.: (201) 342-2020, 1-800-ELSCINT.
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Elscint/France: (1) 48-57-08-18 Elscint/Germany: (01) 22-7070 Elscint/Hong Kong: (5) 292231 Elscint/Israel: (04) 310310 Elscint/Italy: (2) 39320603
The perfect form for Cardiolite

In myocardial perfusion imaging, his form may produce images that are considered technically inadequate because of soft-tissue attenuation.

That's where Cardiolite comes through, especially for female and large-chested or obese male patients. The higher photon energy (140 keV) provides greater anatomical detail that can enhance interpretive confidence—and may reduce false-positives and equivocal cases.

Cardiolite also offers the unique advantage of direct measurement of both myocardial perfusion and ventricular function from one study.

So the next time you're faced with imaging female and large-chested or obese male patients, use Cardiolite and reduce soft-tissue attenuation.

Cardiolite
Kit for the preparation of Technetium Tc99m Sestamibi

To reduce soft-tissue attenuation
Cardiolite comes through

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. © 1994, DuPont Pharma
Cardiolite®
Kit for the preparation of Technetium Tc99m Sestamibi

For Diagnostic Use

DESCRIPTION: Each 5ml vial contains a sterile, non-pyrogenic, lyophilized mixture of:
Technetium (99m) pertechnetate (2 molybdenum isotopic purity) Copper (II) tetracarbomerite - 1.0mg
Sodium Citrate Dihydrate - 2.6mg
L-Cysteine Hydrochloride Monohydrate - 1.6mg
Mannitol - 10mg
Stannous Chloride, Dihydrate, minimum (SnCl2•2H2O) - 0.025mg
Stannous Chloride, Dihydrate, maximum (SnCl2•2H2O) - 0.006mg

Prior to lyophilization the pH is 5.3-5.9. The contents of the vial are lyophilized and stored under nitrogen.

This drug is administered by intravenous injection for diagnostic use after reconstitution with sterile, non-pyrogenic, oxygen-free Sodium Pertechnetate Tc99m. The pH of the reconstituted product is 5.0 (5.0-6.0). No bacteriostatic agent is present.

The precise structure of the technetium complex is Tc99m(MBII)4 where MBII is 2-methoxy isobutyl isonitrile.

INDICATIONS AND USAGE: CARDIOLITE®, Kit for the Preparation of Technetium Tc99m Sestamibi is a myocardial perfusion agent that is useful in the evaluation of ischemic heart disease. CARDIOLITE®, Kit for the Preparation of Technetium Tc99m Sestamibi is useful in distinguishing normal from abnormal myocardium and in the localization of the abnormality, in patients with suspected myocardial infarction, ischemic heart disease or coronary artery disease. Evaluation of ischemic heart disease or coronary artery disease is accomplished using rest and stress techniques.

CARDIOLITE®, Kit for the Preparation of Technetium Tc99m Sestamibi is also useful in the evaluation of myocardial perfusion using the first pass technique.

Rest-exercise imaging with Tc99m Sestamibi in conjunction with other diagnostic information may be used to evaluate ischemic heart disease and its localization.

In clinical trials, using a template consisting of the anterior wall, inferior-posterior wall and isolated apex, technetium Tc99m in wall or inferior postero wall patients with suspected angina pectoris or coronary artery disease was shown. Disease localization isolated to the apex has not been established. Tc99m Sestamibi has not been studied or evaluated in other radiolabeled nuclides.

It is usually not possible to differentiate recent from old myocardial infarction or to differentiate 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 accurate monitoring and treatment in accordance with acceptable clinical procedures. Infract, death has occurred in 1 to 24 hours after Tc99m Sestamibi use and is usually accompanied with exercise stress testing (See Precautions).

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 preparatory 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 maintain radiation protection for the patient consistent with proper patient management.

Contents of the kit before preparation are not radioactive. However, after the Sodium Pertechnetate Tc99m Injection is administered, adequate shielding of the final preparation must be maintained.

The components of the kit are sterile and non-pyrogenic. A kit should be used only if the vial has been unopened and the container is undamaged.

The components of the kit are sterile and non-pyrogenic. A kit should be used only if the vial has been unopened and the container is undamaged.

Stress testing should be performed only under the supervision of a qualified patient 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
- Dyspnea
- Chest Pain
- ST-depression
- Arrhythmia

Cardiogenic, Myocardial, Impairment of Fertility

In comparison with most other diagnostic technetium labeled radiopharmaceuticals, the radiation dose to the ovaries (1.5rad(40/900) at rest, 1.2 rad(90/900) 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 tests. No genotoxicity was observed in the Ames, CHO/HPTP and sister chromatid exchange tests (all in vitro). At cytotoxic concentrations (~200μg/ml), an increase in cells with chromosome aberrations was observed in the in vitro human lymphocyte assay. [Cu(MBII)BF4] did not show genotoxic effects in the mouse micronucleus test or a dose which caused systemic and bone marrow toxicity (9mg/kg > 400 radiosensitive cells).

Pregnancy Category C

Animal reproduction and teratogenicity studies have not been conducted with Technetium Tc99m Sestamibi. It is not known 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 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 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 parasomnia and/or taste perversion (metallic/taste sweet) immediately after the injection of Technetium Tc99m Sestamibi. A few cases of transient headache, flushing, edema, injection site inflammation, dysgeusia, nausea, vomiting, pruritus, rash, urticaria, dry mouth, fever, dizziness, fatigue, dyspnea, and hypotension also have been attributed to administration of the agent. Cases of angioedema, fever, and death have occurred (see Warnings and Precautions). The following adverse reactions have rarely been reported: signs and symptoms consistent with seizure occurring shortly after administration of the agent, transient arhythmia in a 1-2 hour period, and severe hypersensitivity, which was characterized by dyspnea, hypotension, bradycardia, asthma and vomiting within two hours after a second injection of Technetium Tc99m Sestamibi.

DOSAGE AND ADMINISTRATION: The dose suggested range for IV. administration in a single dose of 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.

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>mGy</td>
<td>mGy</td>
</tr>
<tr>
<td>30mCi</td>
<td>1110MBq</td>
<td>1110MBq</td>
</tr>
<tr>
<td>Breasts</td>
<td>0.2</td>
<td>0.2</td>
</tr>
<tr>
<td>Gallbladder Wall</td>
<td>2.0</td>
<td>2.0</td>
</tr>
<tr>
<td>Small Intestine</td>
<td>3.0</td>
<td>3.0</td>
</tr>
<tr>
<td>Upper Large Intestinal Wall</td>
<td>5.4</td>
<td>5.4</td>
</tr>
<tr>
<td>Lower Large Intestinal Wall</td>
<td>3.9</td>
<td>4.2</td>
</tr>
<tr>
<td>Stomach</td>
<td>0.6</td>
<td>0.6</td>
</tr>
<tr>
<td>Heart Wall</td>
<td>0.5</td>
<td>0.5</td>
</tr>
<tr>
<td>Kidney</td>
<td>2.0</td>
<td>2.0</td>
</tr>
<tr>
<td>Liver</td>
<td>0.6</td>
<td>0.6</td>
</tr>
<tr>
<td>Large Intestine</td>
<td>2.2</td>
<td>2.7</td>
</tr>
<tr>
<td>Bone Surfaces</td>
<td>0.7</td>
<td>0.7</td>
</tr>
<tr>
<td>Thyroid</td>
<td>0.7</td>
<td>0.7</td>
</tr>
<tr>
<td>Ovaries</td>
<td>1.5</td>
<td>1.6</td>
</tr>
<tr>
<td>Testes</td>
<td>0.3</td>
<td>0.4</td>
</tr>
<tr>
<td>Red Marrow</td>
<td>0.5</td>
<td>0.5</td>
</tr>
<tr>
<td>Urinary Bladder Wall</td>
<td>0.5</td>
<td>0.5</td>
</tr>
<tr>
<td>Total Body</td>
<td>0.5</td>
<td>0.5</td>
</tr>
</tbody>
</table>

RADIATION DOSIMETRY: The radiation dose to organs and tissues of an average patient (78kg) in 1110MBq (30mCi) of Technetium Tc99m Sestamibi injected intravenously are shown in Table 4.

HOW SUPPLIED: Du Pont Radiopharmaceuticals’ CARDIOLITE®, Kit for the Preparation of Technetium Tc99m Sestamibi is supplied as a 5ml vial in kits of two (2), five (5) or thirty (30) vials, sterile and non-pyrogenic.

Prior to lyophilization the pH is 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 packaging materials included in each package. It contains one (1) package insert, six (6) vial field labels and six (6) radiation warning labels. Included in each five (5) vial kit are one (1) package insert, six (6) vial field labels and six (6) radiation warning labels. Included in each thirty (30) vial kit are one (1) package insert, thirty (30) vial field labels and thirty (30) radiation warning labels.

The U.S. Nuclear Regulatory Commission has approved this reagent kit for distribution to pharmacies licensed to use byproduct pharmaceutical pursuant to section 35.11 and section 35.200 of Title 10 CFR Part 35.

Marketed by Du Pont Radiopharmaceutical Division
The Du Pont Merck Pharmaceutical Co.
631 Trickle Road
Billerica, Massachusetts, USA 01822

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Printed in U.S.A.

Circle Reader Service No. 34
This program is designed for nuclear medicine physicians, radiologists, technologists and referring physicians. It is intended to educate participants about the clinical utility of SPECT brain imaging with agents such as Ceretec® and Neurolite®.

Objectives include:
- Development of interpretation skills for brain images.
- Appreciation of clinical applications of SPECT brain imaging.
- Knowledge of image acquisition and reconstruction.
- Appreciation of factors that influence image quality.
- Knowledge of quality control techniques for SPECT.

SPONSORSHIP:
This program is sponsored by the Medical College of Wisconsin.

TUITION:
The tuition fee of $650 includes the course syllabus, handouts, breaks, breakfasts, lunches, and other amenities involved in making this a pleasant learning experience. Maximum enrollments have been established. Cancellations prior to the course will be refunded, less a $30 administrative fee.

CREDIT:
The Medical College of Wisconsin is accredited by the Accreditation Council for Continuing Medical Education to sponsor continuing medical education for physicians.

Accordingly, the Medical College of Wisconsin designates this continuing medical education activity as meeting the criteria for 13.00 hours in Category 1 toward the Physician’s Recognition Award of the American Medical Association.

Nuclear Medicine Technologists who attend the SPECT Brain Imaging Clinical Fellowship are eligible for 1.0 VOICE credit.

Register me for the following dates: (Please indicate a second choice)
- November 14-15, 1994
- March 13-14, 1995
- January 23-24, 1995
- September 11-12, 1995
- November 13-14, 1995

I will need reservations for Sunday and Monday night _________
Or Monday night only ________________

I will need a __________________ single / __________________ double room.

A check in the amount of $650 should accompany this registration form and be made payable to the Medical College of Wisconsin. Telephone registrations must be confirmed by check within 10 days.

Name __________________________________________
Address _________________________________________
City/State/Zip ____________________________
Office Phone ____________________________

☐ work address ☐ home address

Registrations and payment should be sent to:
LisaAnn Trembeth
SPECT Brain Imaging Fellowship Coordinator
Nuclear Medicine Division
Medical College of Wisconsin
8700 W. Wisconsin Avenue,
Milwaukee, WI 53226 • (414) 777-3756

The 1995 Scientific Program Committee, Scientific Exhibits Subcommittee and the Scientific & Teaching Sessions Committee solicit the submission of abstracts from members and nonmembers of The Society of Nuclear Medicine for the 42nd Annual Meeting in Minneapolis, MN. Accepted Scientific Paper and Scientific Exhibit abstracts will be published in a special supplement to the May issue of the Journal of Nuclear Medicine and accepted Technologist Section abstracts will be published in the June issue of the Journal of Nuclear Medicine Technology. Original contributions on a variety of topics related to nuclear medicine will be considered, including:
- Instrumentation and Data Analysis
- Radioassay
- Radiopharmaceutical Chemistry
- Dosimetry/Radiobiology
- Nuclear Magnetic Resonance Chemistry
- Clinical Science Applications:
  - Bone/Joint
  - Cardiovascular (clinical, basic, and PET)
  - Endocrine
  - Gastroenterology
  - Neurosciences: Basic, Neurology and Psychiatry
  - Pediatrics
  - Pulmonary
  - Renal/Electrolyte/Hypertension
  - Hematology/Infectious Disease
  - Oncology Diagnosis (antibody)
  - Oncology Diagnosis (non-antibody)
  - Oncology/Therapy

Authors seeking publication for the full text of their papers are strongly encouraged to submit their work for immediate review to JNM and for the technologist section, to JNMT.

There are two abstract forms for the annual meeting. The Scientific Paper abstract form and the Scientific Exhibits abstract form is only available by calling or writing to:

Society of Nuclear Medicine
Att: Abstracts
1850 Samuel Morse Drive
Reston, VA 22090-5316
Tel: (703)708-9000 • FAX: (703)708-9015

DEADLINE FOR RECEIPT OF ABSTRACTS FOR SCIENTIFIC PAPERS IS WEDNESDAY, JANUARY 4, 1995.

DEADLINE FOR RECEIPT OF ABSTRACTS FOR SCIENTIFIC EXHIBITS IS WEDNESDAY, JANUARY 4, 1995.
Introducing

A New Way to Image Neuroendocrine Tumors
Somatostatin Receptor Imaging for Neuroendocrine Tumors

Somatostatin is an endogenous neuropeptide that acts as a regulator of growth hormone secretion. Neuroendocrine tumors contain a high density of somatostatin receptors. OctreoScan®, a radiolabeled form of the somatostatin analog octreotide, shares the same binding site as naturally occurring somatostatin, which makes it a sensitive indicator for somatostatin receptor-bearing neuroendocrine tumors. Since the concentration of receptors on tumors may vary, the sensitivity of OctreoScan® may vary among tumor types.

Enhances Neuroendocrine Tumor Localization

Neuroendocrine tumors generally are small and slow-growing in nature, which can make localization difficult. Functional imaging with OctreoScan® frequently is sensitive enough to enable localization of small primary tumors or metastases. In a multicenter study, OctreoScan® results were consistent with the final diagnosis in 86.4% of patients (267/309).* OctreoScan imaging results produced a change in patient management in 31.1% of cases (64/206).*

*Source: Data on file, Mallinckrodt Medical, Inc.
**Patient Management Benefits**

OctreoScan® whole-body imaging enables rapid localization of the primary neuroendocrine tumor and sites of metastatic spread. OctreoScan® imaging also provides tumor localization and characterization information that can help determine the extent of a patient's disease accurately, which may obviate the need for additional invasive procedures such as biopsy or angiography.

OctreoScan® imaging may enable clinicians to modify a patient's diagnostic work-up and initiate appropriate measures (resection, octreotide therapy) at an early stage of the disease process. OctreoScan® also can be used for patient follow-up to monitor the effects of surgery, radiotherapy, or chemotherapy.

---

**Clinical Impact of OctreoScan® Imaging**

<table>
<thead>
<tr>
<th>Description</th>
<th>Percentage</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yielded information about localizations not known before</td>
<td>27.9%</td>
<td>57/204</td>
</tr>
<tr>
<td>Demonstrated uptake in lesions known to exist, but not verified as neuroendocrine tumors</td>
<td>28.2%</td>
<td>55/195</td>
</tr>
<tr>
<td>Localized neuroendocrine tumors in patients with clinical and hormonal evidence of tumor but no prior localizations</td>
<td>37.5%</td>
<td>21/56</td>
</tr>
</tbody>
</table>

---

**Special Considerations**

Adverse effects observed in clinical trials (at a frequency of <1%) included dizziness, fever, flush, headache, hypotension, changes in liver enzymes, joint pain, nausea, sweating and weakness. Pentetreotide is an analog of octreotide, which has been shown to produce severe hypoglycemia in insulinoma patients. In patients suspected of having an insulinoma, an IV solution containing glucose should be administered before and during OctreoScan® administration. Patients should be well hydrated prior to OctreoScan® administration to enhance renal clearance and reduce the radiation dose to the bladder and other target organs. Use in patients with impaired renal function should be carefully considered.

The sensitivity of OctreoScan® scintigraphy may be reduced in patients concurrently receiving therapeutic doses of octreotide acetate. Consideration should be given to suspending octreotide therapy before OctreoScan® administration and monitoring the patient for signs of withdrawal.

Please consult the following page for a brief summary of prescribing information.
**Brief Summary of Prescribing Information**

**Description**
OctreoScan® is a kit for the preparation of indium-111 pentetreotide, a diagnostic radiopharmaceutical. It is a kit consisting of two components:

1. A 10-ml OctreoScan Reaction Vial which contains a lyophilized mixture of 10 g of pentetreotide.

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

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

**Contraindications**
None known.

**Warnings**
DO NOT ADMINISTER IN TOTAL PARENTERAL NUTRITION (TPN) ADJUNCTS OR INJECT INTO TPV INTRAVENOUS ADMINISTRATION LINES; IN THESE SITUATIONS, A COMPLEX GLOUCOSYDIOCTEOL CONJUGATE MAY FORM.

The sensitivity of indium-111 pentetreotide to drugs or manoeuvres of the gastrointestinal tract is not known. Therefore, indium-111 pentetreotide should not be administered to a patient unless the gastrointestinal function is impaired.

**Precautions**

1. Therapy with pentetreotide can produce severe hypoglycaemia in patients with insulinaemia. Since pentetreotide is an analog of octreotide, an intravenous line is recommended in any patient suspected of having an insulinaemia. An intravenous solution containing glucose should be administered just before and during administration of indium-111 pentetreotide.

2. The contents of the two vials supplied with the kit are intended only for use in the preparation of indium-111 pentetreotide and are NOT to be administered separately to the patient.

3. Since indium-111 pentetreotide is eliminated primarily by renal excretion, use in patients with impaired renal function should be carefully considered.

4. To help reduce the radiation dose to the thyroid, kidneys, bladder, and other target organs, patients should be well hydrated before the administration of indium-111 pentetreotide. They should increase fluid intake and void frequencies for 1 week after administration of this drug. In addition, if it is recommended that patients be given a mild laxative (e.g., bisacodyl or lactulose) before and after administration of indium-111 pentetreotide (see Dosage and Administration section).

5. Indium-111 pentetreotide should be tested for labeling yield of radioactivity prior to administration. The product must be used within 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-111 pentetreotide.

7. Pentetreotide and the natural somatostatin hormone may be associated with cholestasis, presumably by altering the composition and possibly by decreasing motility of the gallbladder. A single dose of indium-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.

**Radiopharmaceuticals should be used only by physicians who are qualified by specific training in the safe use and handling of radiopharmaceuticals.**

**Pharmacotherapeutic**

**NEUROENDOCRINE TUMORS**

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

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

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

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

**Adverse Reactions**
The following adverse effects were observed in clinical trials at a frequency of less than 1% of 586 patients: dizziness, fever, flush, headache, hypotension, changes in liver enzymes, joint pain, nausea, sweating, and weakness. These adverse effects were transient. Also in clinical trials, there was one reported case of isostrenodan 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 maximum dose for indium-111 pentetreotide is approximately 200 to 2000 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, confusion, gastritis, vomiting, pain hypertension, and hypercalcemia. These reactions have 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 excretion and the bowel-clearing process. In a patient with an insulinaemia, bowel-clearing should be undertaken only after consultation with an endocrinologist.

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

The dose should be confirmed by a suitably calibrated radioactivity monitoring chamber immediately before administration. As with all intravenously administered products, OctreoScan should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Preparations containing particulate matter or discoloration should not be administered. They should be disposed of in a safe manner, in compliance with applicable regulations.

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

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

**Radiation Dosimetry**

The estimated radiation dose to the average adult (70 kg) from intravenous administration of 111 MBq (3 mCi) and 222 MBq (6.0 mCi) are presented below. These estimates were calculated by Oak Ridge Associated Universities using the data published by Kenning et al.

<table>
<thead>
<tr>
<th>PKNENT</th>
<th>PLANAR</th>
<th>SPECT</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>Urus</td>
<td>8.34</td>
<td>0.63</td>
</tr>
<tr>
<td>Ovaries</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>Bladder</td>
<td>3.46</td>
<td>0.36</td>
</tr>
<tr>
<td>B Bowman</td>
<td>5.67</td>
<td>0.57</td>
</tr>
<tr>
<td>Small Intestine</td>
<td>4.78</td>
<td>0.48</td>
</tr>
<tr>
<td>Upper Large Intestine</td>
<td>5.80</td>
<td>0.58</td>
</tr>
<tr>
<td>Lower Large Intestine</td>
<td>7.73</td>
<td>0.77</td>
</tr>
<tr>
<td>Adrenal</td>
<td>7.55</td>
<td>0.76</td>
</tr>
<tr>
<td>Thyroid</td>
<td>7.43</td>
<td>0.74</td>
</tr>
</tbody>
</table>

**Effective Dose Equivalent**

5.13

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


3. Assumed 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 0019-0005, is supplied with the following components:

1. A 10-ml OctreoScan Reaction Vial which contains a hypothesized mixture of:
   - 10 g pentetreotide (N-(dihydroxyethylene-N,N,N',N"-tetraacetic acid-H\(^{6}\)-acetyl-D-phenylanilaminoL-h-N-amidinol-H,N-amidinol-D-phenylanilamino-L-h-N-amidinol (2 - 7 diafluoro), also known as octreotide DTPA), 2.0 mg gentic acid (2-5-dihydroxybenzoic acid).
   - 4.5 mg indium chloride, anhydrous.
   - 0.03 mg citric acid, anhydrous, and
   - 0.10 mg nien.

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

2. A 10-ml vial of Indium-111 Chloride Sterile Solution, which contains 1.1 ml of 111 MBq/m (0.3 mCi/mL) Indium-111 chloride as 0.02 N HCl at time of calibration. The vial also contains ferric chloride at a concentration of 2.5 mM, ferric ion, 1.2 mCi/mL. The vials are sterile and nonpyrogenic. No bacteriostatic preservative is present.

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

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

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Iobenguane Sulfate I-131 Injection
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When you combine the advantages of whole body imaging with the unique functional specificity of I-131 MIBG, you can localize extra-adrenal and metastatic pheochromocytoma in the preliminary diagnostic work-up. What's more, you can use the high sensitivity and specificity of I-131 MIBG for better management of neuroblastoma patients.

I-131 MIBG gives you a degree of diagnostic confidence simply not possible with non-radionuclide imaging techniques.

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The Service Difference

Please see brief summary of prescribing information on reverse page.

Circle Reader Service No. 25
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For more information: 1-800-221-7554

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CIS-US, Inc.

10 De Angelo Drive, Bedford, MA 01730

Distributed by:

Synchrony

Table 4: Estimated Absorbed Radiation Doses: Iobenguane Sulfate I-131

<table>
<thead>
<tr>
<th>Organ</th>
<th>Adult</th>
<th>18 Years</th>
<th>15 Years</th>
<th>10 Years</th>
<th>5 Years</th>
<th>1 Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>card</td>
<td>mSv</td>
<td>mSv</td>
<td>mSv</td>
<td>mSv</td>
<td>mSv</td>
<td>mSv</td>
</tr>
<tr>
<td>Kidney</td>
<td>29.6</td>
<td>2.96</td>
<td>1.85</td>
<td>1.78</td>
<td>2.78</td>
<td>2.6</td>
</tr>
<tr>
<td>Liver</td>
<td>29.2</td>
<td>2.92</td>
<td>1.85</td>
<td>1.96</td>
<td>2.06</td>
<td>2.06</td>
</tr>
<tr>
<td>Spleen</td>
<td>21.8</td>
<td>2.18</td>
<td>1.57</td>
<td>1.57</td>
<td>2.41</td>
<td>2.41</td>
</tr>
<tr>
<td>Heart</td>
<td>14.1</td>
<td>1.41</td>
<td>0.91</td>
<td>1.41</td>
<td>1.41</td>
<td>2.22</td>
</tr>
<tr>
<td>Adrenal Medulla</td>
<td>0.79</td>
<td>0.79</td>
<td>0.54</td>
<td>0.80</td>
<td>0.80</td>
<td>1.07</td>
</tr>
<tr>
<td>Gallbladder</td>
<td>0.52</td>
<td>0.30</td>
<td>0.30</td>
<td>0.43</td>
<td>0.43</td>
<td>0.67</td>
</tr>
<tr>
<td>Pancreas</td>
<td>4.1</td>
<td>0.41</td>
<td>0.24</td>
<td>0.24</td>
<td>0.38</td>
<td>0.38</td>
</tr>
<tr>
<td>Thyroid</td>
<td>3.3</td>
<td>0.34</td>
<td>0.26</td>
<td>0.26</td>
<td>0.41</td>
<td>0.41</td>
</tr>
<tr>
<td>Kidneys</td>
<td>3.3</td>
<td>0.30</td>
<td>0.20</td>
<td>0.30</td>
<td>0.31</td>
<td>0.48</td>
</tr>
<tr>
<td>Uterus</td>
<td>0.33</td>
<td>0.33</td>
<td>0.20</td>
<td>0.33</td>
<td>0.33</td>
<td>0.52</td>
</tr>
<tr>
<td>Ovaries</td>
<td>0.27</td>
<td>0.27</td>
<td>0.17</td>
<td>0.28</td>
<td>0.28</td>
<td>0.43</td>
</tr>
<tr>
<td>Testes</td>
<td>0.23</td>
<td>0.23</td>
<td>0.14</td>
<td>0.23</td>
<td>0.23</td>
<td>0.33</td>
</tr>
<tr>
<td>Brain</td>
<td>0.18</td>
<td>0.18</td>
<td>0.11</td>
<td>0.19</td>
<td>0.19</td>
<td>0.31</td>
</tr>
</tbody>
</table>

*ORIE, Radiation Internal Dose Information Center, Radiation Dose Estimates for I-131 MIBG Intraovenous Administration.

The following organs each receive less than 1 rad per procedure:
- bone, small intestine, ileum, large intestine, lung, muscle, red marrow, bone surfaces, skin and thymus.

If 0.5 mCi of Iobenguane Sulfate I-131 is used, the organ burden would be half of the doses listed above. The thyroid gland estimated burden is in the unknown state. When the thyroid gland is blocked with Lugol's solution, uptake is minimal. Peak scans were generally noted at 48 hours post-injection. However, serial scans at 24, 48 and 72 hours post-injection may be needed to optimally define the tumor.

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Iobenguane Sulfate I-131 injection is supplied in a 2 mL, glass vial as a sterile, nonpyrogenic solution containing, at calibration time, 65.1 MBq of Iodine 131 (2.3 mCi) of Iobenguane Sulfate I-131 injection. Store the drug at room temperature (20°C - 25°C). Note:
- do not store at refrigerator temperature.

In conformance with USP recommendations, the Iobenguane Sulfate I-131 preparations should not be used after the expiration date stated on the label.

NDC 0455670100

*This radiopharmaceutical is approved U.S. Food & Drug Administration for use in persons known or suspected to have MIBG-positive tumors. See Instructions 36.608.706 at 12 CFR Part 36, effective April 1, 1987, or equivalent American standards issued by an agreeable agency.

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Clinical image courtesy of Vanderbilt University Medical Center, Nashville, TN

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- Nuclear Pharmaceutical Science and Radiochemistry
- Radiation Protection

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For applications and more information, please contact:
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American Board of Science in Nuclear Medicine
c/o The Society of Nuclear Medicine
1850 Samuel Morse Drive, Reston, Virginia 22090-5316
Tel: (703) 708-9000, ext. 250 • Fax: (703) 708-9015
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