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ADAC raises the standard for nuclear imaging.

Digital Done Right.
EPIC™ Detectors make “total-digital” image chains an essential clinical standard. Enhanced performance, system stability and remote servicing lead to increased productivity. Enabling technology means clinical protocols, like weighted-spatial analysis, 511 keV and other imaging protocols are software-driven, bringing a new ease to system expandability.

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VANTAGE™ technology offers new ways to improve clinical accuracy in thallium and technetium cardiac SPECT imaging. Efficient dual 90° narrow-beam geometries optimize throughput with simultaneous transmission mapping during emission data collection. (*Pending 510k Approval)

A Visual Program Environment.
MacroVision™ is a multi-level, object-driven visual programming language. For the first time, there’s an easy and effective tool for creating customized macros or entire new applications.

See for yourself how ADAC is changing the outcome of nuclear imaging.

For information and video, call 800-538-8531 ext. 2100 (U.S.).
Ease of patient approach is provided by the perfectly balanced spring-arm system.

Flared collimator swivels 360 degrees on the detector arm and meets ANSI Standard N 44.3 for Thyroid Uptakes.

Speed and accuracy in radioscopie Quality Assurance, Quality Control, Wipe Tests, Lab Tests and other clinical uses are accomplished with the built-in well detector system.

Patient and user safety through the use of an isolated transformer to insure a grounded system.

To help you with your decision, which we agree is not an easy one, please read the following carefully. Then give us a call and we'll be pleased to discuss both systems with you further.

Faster than a speeding bullet...More powerful than a microprocessor... Able to test, measure & print with accuracy...

The CAPTUS® 2000 brings the power of the latest in computer technology to your facility. It is matched with a high level 1024 MCA and modern Microsoft® Windows software. plus newly released, expanded applications software, and DeskJet 540 Printer.

It's compliment of tests include an advanced Thyroid program readily adaptable to several protocols, plus: Wipe Testing using an automated peak search, Schilling, Dicopac®, Blood Volume, RBC, and Biocassay.

If it doesn't Count it, Store it, Display it, Print it, and Auto Decay-Correct it, it's not the CAPTUS® 600 Thyroid System.

Designed from the ground up by Capintec's talented engineers, the high-quality CAPTUS® 600 is truly cost-effective for performing Uptakes and Bioassay. With power to handle the heaviest workloads, the CAPTUS 600's 256-channel MCA provides features not found on any other non-computer system. But that's not all. Together with the optional well, you can use the system for Wipe Testing, Blood Volume, Schilling, RBC, Daily, and Chi-Square programs. The CAPTUS 600 features menu-driven operations with easy-to-follow prompts on its large backlit screen.

CAPTUS® 2000 Highlights
1) Computer featuring Intel 486 DX2-66 CPU, 8 MB RAM, 540 MB 11 MS Hard Drive, Quad-speed CD-ROM, plus many other features and upgrade options.

2) New CAPTUS Software Version 3.01, plus MS-Dos 6.22, WFW 3.11, MS Works 3.0 & Money, on CD's.

3) Includes an archiving & retrieval utility that has been upgraded offering greater functionality.

4) The ability to add pre-dose measurements when patients have received previously administered doses.

5) Constancy button added, allowing Constancy Test to be performed by itself and recorded.

6) Allows user to measure an efficiency with any source and records for future use.

7) Compact unique Spring-Arm Floor Stand is ergonomically correct and offers great range of detector movement for ease of patient interaction and positioning.

8) On-Line telephone support for all users offers fast response to technical questions through our toll-free 800 numbers.

9) Free Cs-137 and Eu-152 Rod Sources provided.

Both the CAPTUS 600 and CAPTUS 2000 offer many configurations such as: Table Top and Wall Mounted Systems.

CAPTUS® 600 Highlights
1) Low cost Microprocessor with plenty of flexibility and muscle replaces the CAPTUS 500 system with a new look and many new features.

2) On-screen display of spectrum while counting of all tests.

3) No one wants to be just a number, the CAPTUS 600 allows the patient's name and demographics to be typed in through the keyboard.

4) Like its Big Brother, the CAPTUS 2000, the CAPTUS 600 has the ability to add pre-dose measurements.

5) Automatic peak search identifies nuclides with direct readouts in CPM, DPM, Curies & Bequerel with energy spectrum. Plus user definable protocols for wipes.

6) Expanded QC tests added to the system speeds user through the daily routine.

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1-800-ASK-4-CRC
FAX: 201-825-4829

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CAPINTEC, INC.
6 ARROW ROAD, RAMSEY N.J. 07446
High-resolution 800 x 600 SVGA color graphics enhance displays of all programs, especially the full spectrum visible during all counting procedures.

Menu-driven applications programs perform Thyroid Uptake, Wipe Testing, Bioassay, Blood Volume (I-125 or Cr-51), RBC Survival, Schilling Test (standard and Dicopad®), MCA functions as well as Time Activity curves.

Program speed is enhanced with the use of a track-ball addition to the keyboard.

**THE CAPTUS 2000 THYROID UPTAKE SYSTEM**

Immediate report printing on all procedures with the Hewlett Packard 540 DeskJet printer.

**Flared collimator** swivels 360 degrees on the detector arm and meets ANSI Standard N 44.3 for Thyroid Uptakes.

**THE CAPTUS 600 THYROID UPTAKE SYSTEM**

Speed and accuracy in radioisotope Quality Assurance, Quality Control, Wipe Tests, Lab Tests and other clinical uses are accomplished with the optional well detector system.

Stability and ease of maneuverability are provided by the design of the sturdy base and stand with swivel locking casters to maximize positioning.

**Blue (2.36" x 4.72") LCD Display** with cold cathode lamp, backlit, and 128 x 256 pixel resolution features on-screen prompts and display of a full featured 256 channel MCA with presets, multiple ROI's and configuration archiving.

**Convenient alpha/numeric keypad** for inputting patient name, demographics, etc.

**Immediate report printing** on all procedures with a graphic, high-speed dot matrix, quality printer, easily displaying graphics and data for permanent records.

**Patient and user safety** through the use of an isolated transformer to insure a grounded system.

Please see us at the SNM Annual Meeting. Island #501

Circle Reader Service No. 23
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

Please see us at the SNM Annual Meeting. Island #909
Cardiolite®
Kit for the preparation of Technetium Tc99m Sestamibi

FOR DIAGNOSTIC USE

DESCRIPTION: Each 5ml vial contains a sterile, pyrogenic, lyophilized mixture of 
Tetraakis (5-mercapto-2-isobutyl isothiocyano) Copper (II) trifluoroacetate - 1.0mg 
Sodium Citate Dihydrate - 2.6mg 
L-Cysteine Hydrochloride Monohydrate - 1.0mg 
Mannitol - 20.0mg 
Stannous Chloride, Dihydrate, minimum (SnCl2·2H2O) - 0.025mg 
Sodium Sulfite, (Na2SO3·H2O) – 0.06mg 
Tin Chloride (Stannous and Stannic) Dihydrate, maximum (as SnCl2·H2O) - 0.066mg 

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 Injection. The pH of the reconstituted product is 3.5 (3.0-3.6). No bacteriostatic preservative is present. 

The radioactive structure of the technetium complex is $^{99m}$Tc(MIBI)$^+$ where MIBI is 2-mercapto isobutyryl isothiocyanate.

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 area, concentrations of Tc99m Sestamibi in patients with suspected angina pectoris or coronary artery disease was shown. Disease localization isolated to the aper has not been established.

Tc99m Sestamibi has not been studied or evaluated in other cardiac diseases.

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 perform comparative and monitoring in treatment in accordance with safe, accepted clinical practice. Infrequently, death has occurred 4 to 24 hours after Tc99m Sestamibi use and is usually associated with exercise stress testing (see Precautions).

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 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 minimize radiation exposure to the patients consistent with proper patient management.

Contents of the kit before preparation are non-radioactive. However, after the Sodium Pertechnetate Tc99m injection is added, adequate shielding of the final preparation must be maintained.

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

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

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

Radioopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radionuclides and whose experience and training have been approved by the appropriate government agency authorizing 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 resulted in termination of the test during controlled Tc99m Sestamibi studies (two-thirds were cardiac patients) were: Fatigue, 25%; Dyspnea, 17%; Chest Pain, 11%; ST-depression, 7%; Arrhythmia, 1%.

Carcinogenesis, Mutagenesis, Impairment of Fertility

In comparison with other diagnostic technetium labeled radiopharmaceuticals, the radiation dose to the ovaries (5.35rad/30mCi at rest, 1.2 rad/30mCi at exercise) in minimal. Exposure (ALARA) is necessary in women of childbearing capability. (See Dosimetry subsection in DOSAGE AND ADMINISTRATION section).

The active intermediate, [Cu(MBI)BF], was evaluated for genotoxic potential in a battery of five tests. No genotoxic activity was observed in the Ames, CHO/HPTT and sister chromatid exchange tests. Although some comet (single and double strand) breaks were observed in the human lymphocyte assay, [Cu(MBI)BF] did not show genotoxic effects in the in vivo mouse micronucleus test at a dose which caused systemic and bone marrow toxicity (9mg/kg, > 800 × maximal human dose).

Pregnancy Category C

Animal reproduction and teratogenic studies have not been conducted with Technetium Tc99m Sestamibi. It is also 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 Sestamibi 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.

ADVERSE REACTIONS: During clinical trials, approximately 8% of patients experienced a transient paraesthesia and/or taste perversion (metallic or bitter taste) 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, dyspnea, and hypotension also have been attributed to administration of the agent. Cases of angina pectoris have been reported (see Warnings and Precautions). The following adverse reactions have been rarely reported: signs and symptoms consistent with seizure occurring shortly after administration of the agent; transient atrichia in a hair; and severe hypersensitivity, which was characterised 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 IV. administration in a single dose is to:

- 670-1110MBq (18-30mCi) for adults
- 370-1110MBq (10-30mCi) for children

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. Radioactivity purity should be checked prior to patient administration.

Parenteral drug products should be visually inspected for particulate matter and discolouration 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 an average patient (70kg) per 1110MBq (30mCi) of Technetium Tc99m Sestamibi injected intravenously are shown in Table 4.

<table>
<thead>
<tr>
<th>Table 4. Radiation Absorbed Doses from Tc99m Sestamibi</th>
</tr>
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<tbody>
<tr>
<td>Organ</td>
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<tr>
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<td>--------------------------------------------------</td>
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<tr>
<td><strong>2.0 hour void</strong></td>
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<td>--------------------------------------------------</td>
</tr>
<tr>
<td><strong>REST</strong></td>
</tr>
<tr>
<td>--------------------------------------------------</td>
</tr>
<tr>
<td>Breasts</td>
</tr>
<tr>
<td>Gallbladder Wall</td>
</tr>
<tr>
<td>Small Intestine</td>
</tr>
<tr>
<td>Upper Large Intestine Wall</td>
</tr>
<tr>
<td>Lower Large Intestine Wall</td>
</tr>
<tr>
<td>Heart Wall</td>
</tr>
<tr>
<td>Liver</td>
</tr>
<tr>
<td>Bone Surfaces</td>
</tr>
<tr>
<td>Thymus</td>
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<tr>
<td>Ovaries</td>
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<tr>
<td>Testes</td>
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<tr>
<td>Red Marrow</td>
</tr>
<tr>
<td>Urinary Bladder Wall</td>
</tr>
<tr>
<td>Total Body</td>
</tr>
</tbody>
</table>

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) and thirty (30) vials, sterile and non-pyrogenic.

Prior to lyophilization 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 33.11 and 33.200 of Title 10 CFR Part 35, to persons who hold an equivalent license issued by an Agreement State, and, outside the United States, to persons authorized by the appropriate authority.

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With the new PRISM™ 1500 XP from Picker, you can image patients without moving them from their transport gurney or hospital bed.

This open gantry, cantilevered, single-head nuclear imaging system is ideal for a broad range of clinical exams, from nuclear cardiology applications to planar, whole-body, and SPECT imaging.

And its open design and across-the-table reach offer easy access, even when you’re working with critically ill patients.

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**Computers in Nuclear Medicine: A Practical Approach**
Kai Lee, PhD
$30 members/$42 non-members. This illustrated guide explains both how computers work and how processing techniques obtain diagnostic information from radionuclide images.

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Pamphlet, $0.40 (100 copies, minimum order). This popular pamphlet explains nuclear medicine procedures in clear, concise language, helping to allay patient anxieties. Format includes common questions and answers; step-by-step descriptions of procedures; photographs showing patients undergoing imaging. An update of the highly successful patient pamphlet in use since 1983.

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Wanda M. Mundy, EdD, CNMT and Gregory Passmore, MS, CNMT
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Open MULTISPECT™ 2 with 511 keV collimator

High Energy Imaging Focus for 21st Century Medicine

As the emphasis of diagnostic medicine shifts from structural abnormality to molecular dysfunction, Nuclear Medicine can discern what some can’t see and answer questions others don’t hear.

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- The most exacting PET with the ECAT HR+

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*Use of $^{18}$FDG requires FDA approval.

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New from DuPont Radiopharmaceuticals:
High Quality and Extended Stability
in a SPECT Brain Perfusion Agent

JUST WHAT YOU'RE LOOKING FOR...
Introducing a NEW SPECT Brain Perfusion Agent

NEUROLITE
KIT FOR THE PREPARATION OF TECHNETIUM Tc99m BICISATE INJECTION

Technetium Tc99m Bicisate should be used with caution in patients with renal or hepatic impairment since it is eliminated primarily by renal excretion. Adverse reactions are rare (≤1%). For details, see Adverse Reactions section of the prescribing information. In clinical trials, at least one of three readers of Neurolite® images (blinded to all other clinical information) correctly diagnosed stroke for 85% of the subjects with stroke while unblinded interpretation of CT/MRI images resulted in the correct diagnosis of stroke in 88% of subjects with stroke. There were 11 false positive and 34 false negative interpretations of Neurolite images and 0 false positive and 31 false negative interpretations of CT/MRI results.

Normal images, using Neurolite, of a 36-year-old female.
— Courtesy of Thomas C. Hill, MD.
Deaconess Hospital, Boston, Mass
Just what you’re looking for...

HIGH-QUALITY IMAGES...
EXTENDED STABILITY...

High-Definition Perfusion Images
Well-defined lesions
☀ Clear definition of perfusion defects as determined by visual analysis

High brain-to-background activity
☀ Clear delineation between brain and background structures early after injection

Extended In Vitro Stability
The SPECT brain agent with 6-hour stability after preparation
☀ Allows for more flexible patient scheduling
☀ Useful in the acute setting since doses can be prepared beforehand
☀ Enables SPECT brain imaging to be used with agitated or uncooperative patients where study delays are often encountered
☀ Allows for convenience of unit dosing

Please see brief summary of prescribing information at the end of this advertisement.
JUST WHAT YOU’RE LOOKING FOR...

Desirable pharmacokinetics/dosimetry

- Accumulates rapidly in the brain\(^1,2\)
- Localizes as a function of regional brain perfusion, cellular uptake, and metabolism within the cells
- Rapid blood clearance—(< 10\% remains in the blood after 1 minute, <5\% after 60 minutes)
- A dosing range of 10-30 mCi of Neurolite provides the flexibility to achieve improved image quality and/or reduced imaging time\(^1\)

Simple room-temperature preparation
One-step quality control procedure

NEUROLITE
KIT FOR THE PREPARATION OF TECHNETIUM Tc\(^{99}\)m BICISATE INJECTION

Quality you expect. Stability you need.
The following is a brief summary. For more information please see complete prescribing information.

INDICATIONS
Neurolite single photon emission computed tomography (SPECT) is indicated as an adjunct to conventional CT or MRI imaging in the localization of stroke in patients in whom stroke has already been diagnosed.

Neurolite is not indicated for assessment of functional viability of brain tissue. Also, Neurolite is not indicated for distinguishing between stroke and other brain lesions.

CONTRAINDICATIONS
None known.

WARRANTIES
None known.

PRECAUTIONS

General
USE WITH CAUTION IN PATIENTS WITH RENAL OR HEPATIC IMPAIRMENT. TECHNETIUM Tc99m BICISATE IS ELIMINATED PRIMARILY BY RENAL EXCRETION. ADJUSTMENTS IN PATIENTS WITH RENAL OR HEPATIC IMPAIRMENT HAVE NOT BEEN STUDIED.

Patients should be encouraged to drink fluids and to void frequently during the 2-6 hours immediately after injection to maximize radiation dose to the bladder and other target organs.

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

The contents of each vial are sterile and nonpyrogenic. To maintain sterility, aseptic technique must be used during all operations in the manipulation and administration of Neurolite.

Technetium Tc99m Bicisate should be used within six hours of the time of preparation.

As with any other radioactive material, appropriate shielding should be used to avoid unnecessary radiation exposure to the patient, occupational workers, and other people.

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

Carcinogenesis, Mutagenesis, Impairment of Fertility
Studies have not been conducted to evaluate carcinogenic potential or effects on fertility. When tested in vitro, Neurolite prepared with decayed generator eluate induced unscathed DNA synthesis in rat hepatocytes and caused an increased frequency of sister chromatid exchanges in CHO cells; but, it did not induce chromosomal aberrations in human lymphocytes or cause gene mutations in the Ames test or in a CHO/HGPRT test. Unreacted bicisate dihydrochloride increased the apparent rate of gene mutation of the TA 97a strain of S. typhimurium in the Ames test; but, it did not demonstrate clastogenic activity in an in vivo micronucleus assay in mice.

Pregnancy: Teratogenic Effects
Pregnancy Category C
Animal reproduction studies have not been conducted with Technetium Tc99m Bicisate. It is also not known whether Technetium Tc99m Bicisate can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Therefore, Technetium Tc99m Bicisate 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 children have not been established.

ADVERSE REACTIONS
In clinical trials, Neurolite has been administered to 1022 subjects (262 normals, 760 patients). Of these, 548 (54%) were men and 473 (46%) were women. The mean age was 58 years (range 17 to 92 years). In the 760 patients who had experienced neurologic events, there were 11 (1.4%) deaths, none of which were clearly attributed to Neurolite.

A total of 60 subjects experienced adverse reactions; the adverse reaction rates were comparable in the <65 year and the >65 year age groups.

The following adverse effects were observed in ≤1% of the subjects: headache, dizziness, seizure, agitation/anxiety, malaise/somnolence, parosmia, hallucinations, rash, nausea, syncope, cardiac failure, hypertension, angina, and agnos/cyanosis.

In clinical trials of 197 patients, there were inconsistent changes in the serum calcium and phosphate levels. The cause of the changes has not been identified and their frequency and magnitude have not been clearly characterized. None of the changes required medical intervention.

DOSAGE AND ADMINISTRATION
Before administration, a patient should be well hydrated. After administration, the patient should be encouraged to drink fluids liberally and to void frequently.

The recommended dose range for intravenous administration for a 70 kg patient is 370 - 1110 MBq (10-30 mCi). Dose adjustments for age, weight, gender, or renal or hepatic impairment have not been studied.

The dose for the patient should be measured by a suitable radioactivity calibration system immediately before administration to the patient. Radiochemical purity should be checked before administration to the patient.

Neurolite, like other parenteral drug products, 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 all applicable regulations.

Prior to reconstitution, vial A and vial B are stored at 15°-25°C. Protect vial A from light.

Store at room temperature (15°-30°C) after preparation.

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

RADIATION DOSE

The radiation doses to organs and tissues of a normal patient (70 kg) for Technetium Tc99m Bicisate injected intravenously for 370 MBq (10 mCi) are shown in Table 4 and for 1110 MBq (30 mCi) are shown in Table 5.

Table 4.—Radiation Absorbed Doses From 370 MBq (10 mCi) of Technetium Tc99m Bicisate

<table>
<thead>
<tr>
<th>Organ</th>
<th>2.0 Hr. Void</th>
<th>2.0 Hr. Void</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>mCi/MBq</td>
<td>rads/MBq</td>
</tr>
<tr>
<td></td>
<td>370 MBq</td>
<td>10 mCi</td>
</tr>
<tr>
<td></td>
<td>370 MBq</td>
<td>10 mCi</td>
</tr>
<tr>
<td>Bone Surfaces</td>
<td>1.26</td>
<td>0.13</td>
</tr>
<tr>
<td>Brain</td>
<td>2.04</td>
<td>0.20</td>
</tr>
<tr>
<td>Gallbladder Wall</td>
<td>9.25</td>
<td>0.91</td>
</tr>
<tr>
<td>Intestine Wall (Small)</td>
<td>4.81</td>
<td>0.47</td>
</tr>
<tr>
<td>Intestine Wall (Large)</td>
<td>3.48</td>
<td>0.35</td>
</tr>
<tr>
<td>Kidneys</td>
<td>2.70</td>
<td>0.27</td>
</tr>
<tr>
<td>Liver</td>
<td>1.96</td>
<td>0.20</td>
</tr>
<tr>
<td>Lungs</td>
<td>0.74</td>
<td>0.08</td>
</tr>
<tr>
<td>Ovaries</td>
<td>2.00</td>
<td>0.22</td>
</tr>
<tr>
<td>Red Marrow</td>
<td>0.89</td>
<td>0.09</td>
</tr>
<tr>
<td>Testes</td>
<td>0.81</td>
<td>0.08</td>
</tr>
<tr>
<td>Thyroid</td>
<td>1.30</td>
<td>0.13</td>
</tr>
<tr>
<td>Urinary Bladder Wall</td>
<td>11.91</td>
<td>1.10</td>
</tr>
<tr>
<td>Total Body</td>
<td>0.89</td>
<td>0.09</td>
</tr>
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Table 5.—Radiation Absorbed Doses From 1110 MBq (30 mCi) of Technetium Tc99m Bicisate

<table>
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<tr>
<th>Organ</th>
<th>2.0 Hr. Void</th>
<th>2.0 Hr. Void</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>mCi/MBq</td>
<td>rads/MBq</td>
</tr>
<tr>
<td></td>
<td>1110 MBq</td>
<td>30 mCi</td>
</tr>
<tr>
<td></td>
<td>1110 MBq</td>
<td>30 mCi</td>
</tr>
<tr>
<td>Bone Surfaces</td>
<td>3.77</td>
<td>0.39</td>
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<tr>
<td>Brain</td>
<td>6.11</td>
<td>0.61</td>
</tr>
<tr>
<td>Gallbladder Wall</td>
<td>27.75</td>
<td>2.73</td>
</tr>
<tr>
<td>Intestine Wall (Small)</td>
<td>14.43</td>
<td>1.41</td>
</tr>
<tr>
<td>Kidneys</td>
<td>10.43</td>
<td>1.05</td>
</tr>
<tr>
<td>Liver</td>
<td>8.10</td>
<td>0.81</td>
</tr>
<tr>
<td>Lungs</td>
<td>5.88</td>
<td>0.60</td>
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<tr>
<td>Ovaries</td>
<td>2.22</td>
<td>0.23</td>
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<tr>
<td>Red Marrow</td>
<td>8.99</td>
<td>0.66</td>
</tr>
<tr>
<td>Testes</td>
<td>2.66</td>
<td>0.26</td>
</tr>
<tr>
<td>Thyroid</td>
<td>3.89</td>
<td>0.39</td>
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<tr>
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<td>3.33</td>
</tr>
<tr>
<td>Total Body</td>
<td>2.66</td>
<td>0.27</td>
</tr>
</tbody>
</table>

Dosimetry calculated using the MIRD software program at Oak Ridge Associated Universities, P.O. Box 117, Oakridge, TN, 29 July 1989.
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CERETEC®
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Ceretec® Kit for the Preparation of Technetium Tc99m Examinezime Injection
Diagnostic radiopharmaceutical – For intravenous use only

DESCRIPTION
The Ceretec kit is supplied as five packs of three vials for use in the preparation of a technetium Tc99m exametezime intravenous isotope as a diagnostic radiopharmaceutical. Each vial of Ceretec contains a pre-dispersed sterile, non-
pyrogenic tyzolipid mixture of 0.5 mg exametezime (IAR.SS-4,8-diaz-3,6,6,9-tetramet
hydridene-2,10-dione bisazine), 7.6 µg stannous chloride dihydrate (minimum stannous tin 0.6 µg; maximum total stannous and stannic tin 0.4 µg per vial) and 4.5 mg sodium chloride, sealed under nitrogen atmosphere with a rubber closure. The product contains no antimicrobial preservative.

In addition, each package contains five 1 ml vials of Methylene Blue Injection USP 1% containing 10 mg methylene blue USP in water for injection q.s., pH adjusted with sodium hydroxide and/or hydrochloric acid, when necessary. Methylene Blue Injection USP is a sterile, non-
pyrogenic solution of phenothiazin-5-um,3,7-bis(dimethylamino)-chloride, trihydroly.
Each package also contains five 4.5 ml vials of 0.003 M Monobasic Sodium Phosphate USP and Dibasic Sodium Phosphate USP 0.9% Sodium Chloride Injection USP. The solution is sterile and non-pyrogenic. Each ml contains 0.276 mg monobasic sodium monohydrate, 0.142 mg dibasic sodium phosphate anhydrous and 9 mg sodium chloride in water for injection q.s. The total calculated osmolarity of the 0.003 M Monobasic Sodium Phosphate USP and Dibasic Sodium Phosphate USP 0.9% Sodium Chloride Injection USP is 317 mOsml/L. Each ml provides 0.285 mg (3mM) of phosphate, 0.157 mg of sodium and 0.154 mg of chloride. When used according to the preparation instructions (see Dosage and Administration), Methylene Blue Sodium Phosphate/Sodium Chloride mixture act as a stabilizer.

INDICATIONS AND USAGE
Technetium Tc99m exametezime scintigraphy (with or without methylene blue stabilization) may be useful as an adjunct in the detection of altered regional cerebral perfusion in stroke. Tc99m exametezime without methylene blue stabilization is indicated for leucocyte labeled scintigraphy as an adjunct in the localization of intra-abdominal infection and inflammatory bowel disease.

CONTRAINDICATIONS
None known.

PRECAUTIONS
As with any injected product, acute hypersensitivity or allergic reactions are possible. Limited reports have been received of hypersensitivity reactions following administration of Tc99m labeled leukocytes prepared using Tc99m exametezime. However, the materials used in leucocyte cell separation may cause hypersensitivity reactions. It is essential that cells are washed free of sedimentation agents before they are reinjected into the patient.

In case of side effects following administration of radiopharmaceuticals, users should ensure the availability of appropriate medical treatment at the time of administration of any radiopharmaceutical to the patient.

A thorough knowledge of the normal distribution of intravenously administered technetium Tc99m exametezime injection is essential in order to interpret pathologic studies accurately. Caution should be exercised in making the final diagnosis. Results can be affected by the presence of tumor, infection, peritonitis, non-gastrointestinal or bony sites of inflammatory cell collections.

The contents of the Ceretec vial are not radioactive. After the sodium pertechnetate Tc99m is added, the product is radioactive and adequate shielding of the final preparation must be maintained. The contents of the Ceretec vial are intended only for use in preparation of technetium Tc99m exametezime injection and are NOT to be administered directly to the patient.

General
The contents of the Ceretec vial are sterile and pyrogen free. The vial contains no bacteriostatic preservative. It is essential that the user follow the directions carefully and adhere to strict aseptic procedures during preparation of the radiopharmaceutical.

Radiopharmaceuticals should be used only by or under the control of physicians who are qualified by training and experience in the safe use and handling of radiopharmaceuticals and whose experience and training have been approved by the appropriate governmental agency authorized to license the use of radionuclides.

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.

Carcinogenesis, Mutagenesis, Impairment of Fertility
Long term animal studies have not been performed to evaluate carcinogenic potential or whether exametezime affects fertility in males or females. When evaluated in the Ames test, exametezime increased the apparent rate of gene mutation in the TA100 strain of S. typhimurium. Exametezime did not cause chromosomal aberrations in vitro (Chinese Hamster Ovary cells) or in vivo (rat bone marrow).

Pregnancy Category C
Animal reproduction studies have not been conducted with Tc99m exametezime. It is also not known whether Tc99m exametezime can cause fetal harm when administered to a pregnant woman or if it can affect reproductive capacity. Therefore, Tc99m exametezime should not be administered to a pregnant woman unless the potential benefit justifies the potential risk to the fetus.

Nursing Mothers
Technetium Tc99m is excreted in human milk during lactation. It is not known whether exametezime is excreted in human milk. Therefore, formula feedings should be substituted for breast feeding for sixty hours.

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

ADVERSE REACTIONS
Rash with generalized urtication, facial edema and fever has been reported in less than 1% of patients. A transient increase in blood pressure was seen in 8% of patients.

Cautionary Notes
1) 0.37 GBq to 2.00 GBq (10 mCi up to 54 mCi) technetium Tc99m may be added to the vial. Before reconstitution the technetium Tc99m generator eluate may be adjusted to the correct radioactive concentration to a volume of 5 ml by dilution with preservative-free, non-bacteriostatic saline for injection.

2) Use only elute from a technetium Tc99m generator which was previously eluted within 24 hours. For brain imaging when using stabilizing protocol, generator eluates more than 30 minutes old should not be used. For the highest radiobiologi
cal purity reconstitute with freshly eluted technetium Tc99m generator eluates. For white blood cell labeling, generator elutes more than 2 hours old should not be used.

3) Radiochemical purity testing must be performed prior to patient administration. A radiochemical purity greater than 80% is necessary for product acceptance.

4) Do not use the final radiopharmaceutical preparation for Ceretec with Methylene Blue stabilizer more than 4 hours after the time of reconstitution. Do not use the final radiopharmaceutical preparation for Ceretec without Methylene Blue stabilizer more than 30 minutes after the time of reconstitution. Discard any unused material.

HOW SUPPLIED
The kit comprises five individual vials of sterile, non-pyrogenic, freeze-dried mixture of exametezime, stannous chloride dihydrate and sodium chloride, ten radiation labels, six sterile alcohol swabs, five radiopharmaceutical purity worksheets, five labeling efficiency worksheets, one package insert, five individual vials of Methylene Blue Injection USP 1%, five individual vials of 0.003 M Monobasic Sodium Phosphate USP and Dibasic Sodium Phosphate USP in 0.9% Sodium Chloride Injection USP and fifteen 0.45 mU syringe filters.

Caution: Federal (U.S.A.) law prohibits dispensing without prescription.

This reagent kit is approved for use by persons licensed by the Illinois Department of Nuclear Safety pursuant to 32 Ill. Code Adm. Section, Section 330.280(x) and 335.4010 or under equivalent licenses of the U.S. Nuclear Regulatory Commission, or an Agreement State.

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JUNE

June 11-15, 1995
42ND ANNUAL MEETING. Sponsor: Society of Nuclear Medicine. Location: Minneapolis Convention Center, Minneapolis, MN. Contact: Alexandra Odekerken, Society of Nuclear Medicine, Attn: Annual Meeting, 1850 Samuel Morse Dr., Reston, Va 22090-5316, (703) 708-9000, ext. 229. Fax: (703) 708-9015.

MEETINGS SPONSORED BY OTHER ORGANIZATIONS

JUNE

June 3-7, 1995
PRINCIPLES AND PRACTICE OF CLINICAL MAGNETIC RESONANCE IMAGING. Sponsor: Johns Hopkins Medical Institutions. Location: Renaissance Hotel, Washington, DC. Fee: Physicians ($575); residents, fellows, technologists ($375). Credit: 22 AMA Category 1 hr. Contact: Conference Coordinator, Johns Hopkins Medical Institutions, Office of Continuing Medical Education, Turner 20, 720 Rutland Ave., Baltimore, MD, 21205 (410) 955-2959.

June 15-17, 1995

July 2-6, 1995

July 3-8, 1995
FIRST INTERNATIONAL CONFERENCE ON FUNCTIONAL MAPPING OF THE HUMAN BRAIN. Sponsor: Service Hospitalier Frédéric Joliot. Location: Paris, France. Contact: B. Mazoyer, Human Brain Map 95, Service Hospitalier Frédéric Joliot, CEA-DRIPP, F-91401 Orsay Cedex, 38-1-69-86-77-12. Fax: 33-1-69-86-77-68. E-mail: mazoyer@uniens.shjf.cea.fr.

July 4-6, 1995
1995 INTERNATIONAL MEETING ON FULLY THREE-DIMENSIONAL IMAGE RECONSTRUCTION IN RADIOLOGY AND NUCLEAR MEDICINE. Sponsor: CEA (French Atomic Energy Agency). Location: Aix les Bains, Savoie, France. Fee: $420-$530. Contact: Pierre Grangeat, Com.G. DSYS, 17 rue des Martyrs, 38054, Grenoble, Cedex 9, France, (33) 76-88-43-73. Fax: (33) 76-88-51-64. E-mail: guillemaud@dsys.ceng.cea.fr.

JULY

The SNM Education and Research Foundation

Student Fellowship Grants—These grants are designed to stimulate interest among students in the United States and Canada in the nuclear medicine field. These awards provide an opportunity to spend elective quarters and/or summers working with experts in the field. Maximum grant is $3000 for three months. Ranking of the candidate will be based on the quality and originality of the research proposal submitted. Applicants must provide the information requested in the application form for consideration. Decisions on candidate’s ranking will be made at the Mid-Winter and Annual Meeting of the Society of Nuclear Medicine. The number of candidates to whom awards are made will be based on the quality and originality of the research proposal submitted. Applications should be submitted to the Secretary-Treasurer of the Society of Nuclear Medicine, 720 Rutland Ave., Baltimore, MD 21205, by December 1, 1995.
will be made is determined by the funds available for student fellowships. Contact: E&R Foundation, Society of Nuclear Medicine, 1850 Samuel Morse Dr., Reston, VA 22090-5316.

**Pilot Research Grants**—These grants are intended to provide seed money to scientists working in the nuclear medicine field. Such proposals must be of a pilot nature in either clinical or basis research. Maximum grant: $5000. Applicants must provide the information requested in the application form for consideration; including justification of why this is a pilot research grant and how it will allow the applicant to fully develop his/her research program. Decisions on such grants, based on available funding, will be made at the Mid-Winter and Annual Meeting of the Society of Nuclear Medicine. Contact: Susan Weiss, CNMT, Administrative Director, E&R Foundation, Society of Nuclear Medicine, 1850 Samuel Morse Dr., Reston, VA 22090-5316.

**Joseph Sternberg Student Fellowship**—Funds for a student fellowship have been donated by friends and family of the late Joseph Sternberg, MD (1912-1991), an endocrinologist-nuclear physician and pioneer of nuclear medicine. Dr. Sternberg was among the first physicians in the world to work with radioactive isotopes. He began his work under a French student fellowship award similar to those awarded by the Society of Nuclear Medicine E&R Foundation. Dr. Sternberg served as vice-president of SNM in 1963 and was instrumental in founding the World Federation of Nuclear Medicine and Biology and the *Journal of Nuclear Medicine and Biology*, where he was the first scientific editor. In recognition of his scientific achievements and his contributions to the establishment of the field of nuclear medicine, a fund has been set up in his memory to further the training of a selected young scientist in nuclear medicine. Contact: E&R Foundation, Society of Nuclear Medicine, 1850 Samuel Morse Dr., Reston, VA 22090-5316.

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**Classified Advertising**

**Positions Available**

**Nuclear Imaging Research and Development**

SMALL EMERGING NIH funded R&D firm filling several positions. Projects include: (1) Development and clinical testing of a compact portable first-pass cardiac camera and associated short-lived generator system and; (2) Development of a short-lived PET generator system for myocardial perfusion and functional brain imaging studies. Positions include: (1) Radiochemist experienced in process of short-lived cyclotron produced radiopharmaceuticals; (2) Software engineer experienced in MS C+, Fortran and Assembly programming in the MS Windows environment; (3) Administrator experienced in management of large NIH funded research projects. Please forward a letter of interest, CV, and list of references to: Jeffery L. Lacy, Ph.D., Proportional Technologies, Inc., 8018 El Rio, Houston, TX 77054.

**Nuclear Radiologist**

NUCLEAR RADIOLoGIST BOARD CERTIFIED IN RADIOLOGY and BC/BE in Nuclear Medicine/Nuclear Radiology to share responsibilities in Diagnostic Radiology and Nuclear Medicine. We are a private teaching hospital practice with radiology residents covering two hospitals with 1,600 total beds. We perform 18,000 nuclear medicine procedures annually, with 30%-35% nuclear cardiology procedures. Modern equipment including dual-head SPECT cameras at both hospitals and a networked computer system. Staff includes 30 radiologists including 4 in nuclear medicine. Mail or fax CV inquiries to: M. Mosnuddin, MD, Mid-South Imaging & Therapeutics, PA, 910 Madison, Suite 704, Memphis, TN 38103. Fax: 901-526-8707.

**Physician**

BE INTERNAL MEDICINE, BE Nuclear Medicine seeks full/part-time position. Well experienced in nuclear cardiology, pediatric nuclear medicine, management of thyroid diseases, as well as PET and SPECT imaging. Available July '95. Please reply to box #603, Society of Nuclear Medicine, 1850 Samuel Morse Drive, Reston, VA 22090.

**Radiologist**

BORED, EARLY RETIREE, board cert. radiologist, wishes to re-enter practice. Formerly director of nucl. med. at Elmhurst (IL) Meml. Hosp. 1968-1986. Far west suburbs of Chicago preferred. Write Dr. James Turner, P.O. Box 1174, St. Charles, IL 60174.
Introducing

A New Way to Image Neuroendocrine Tumors
Introducing Octreoscan®
Kit for the Preparation of Indium In-111 Pentetreotide

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.

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 stabilized mixture of 10 μg pentetreotide.
2) A 10-mL vial of indium-111 Chloride Sterile Solution.

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

INDICATIONS AND USAGE
Indium-111 pentetreotide is an agent for the scintigraphic localization of primary and metastatic neuroendocrine tumors bearing somatostatin receptors.

CONTRAINDICATIONS
None known.

WARNINGS
DO NOT ADMINISTER IN TOTAL PARENTERAL NUTRITION (TPN) ADIXMURES OR INJECT INTO TPN INTRAVENOUS ADMINISTRATION LINES; IN THESE SOLUTIONS, A COMPLEX GLYCOSYL OXIDE.TREOTEITE CONJUGATE MAY FORM.

The sensitivity of scintigraphy with indium-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-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-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 frequency for one day after administration of this drug. In addition, 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. Octreotide acetate and the natural somatostatin hormone may be associated with cholelithiasis, presumably by altering fat absorption and possibly by decreasing motility of the gallbladder. A single dose of indium-111 pentetreotide is not expected to cause cholelithiasis.
8. As with any other radiopharmaceutical, appropriate shielding should be used to avoid unnecessary radiation exposure to the patient, occupational workers, and other persons.
9. Radiochromapharmaceuticals should be used only by physicians who are qualified by specific training in the safe use and handling of radionuclides.

Carcinogenesis, 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 vivo 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 this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when indium-111 pentetreotide is administered to a nursing woman.

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

ADVERSE REACTIONS
The following adverse effects were observed in clinical trials at a frequency of less than 1% of 538 patients: dizziness, fever, flush, headache, hypertension, 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 diuretic-related hypotension and hemoglobin.

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

DOSEAGE AND ADMINISTRATION
Before administration, the 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., bisacodyl or lactulose) be given to the patient starting the evening before the radioactive drug is administered, and continuing for 48 hours. Ample fluid intake is necessary during this period as a support both to renal elimination and the bowel-cleansing process. In a patient with an insulinoma, bowel-cleansing 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 in saturation 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.

PLANTAR

<table>
<thead>
<tr>
<th>Organ</th>
<th>PLANAR</th>
<th>SPECT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kidney</td>
<td>54.16</td>
<td>9.62</td>
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<tr>
<td>Liver</td>
<td>12.15</td>
<td>2.43</td>
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<tr>
<td>Spleen</td>
<td>73.76</td>
<td>14.77</td>
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<tr>
<td>Uterus</td>
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<tr>
<td>Ovaries</td>
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<tr>
<td>Testes</td>
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<td>Red Marrow</td>
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<td>Urinary</td>
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<td>Small Intestine</td>
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<td>Adrenal</td>
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<td>1.51</td>
</tr>
<tr>
<td>Thyroid</td>
<td>7.43</td>
<td>1.49</td>
</tr>
</tbody>
</table>

Effective Dose

0.135 ng/kg/kg

1. Values listed include a correction for a maximum of 0.1% indium-114m radiocountant 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 0019-9090, is supplied with the following components:

1. A 10-mL OctreoScan Reaction Vial which contains a lyophilized mixture of (i) 10 μg pentetreotide (N-[d-tyrosylamine-N,N,N'-tetraacetic acid-N'-acetyl-D-phenylalanyl-L-hemicyclic-L-threonin cyclic (2-7) dipeptide], also known as octreotide DTPA), (ii) 2.0 mg gentamic acid (2.5-dihydroxybenzoic acid), (iii) 4.3 mg sodium citrate, anhydrous, (iv) 0.07 mg citric acid, anhydrous, and (v) 10.0 mg inositol.

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

2. A 10-mL vial of indium-111 Chloride Sterile Solution, which contains 1.1 mL of 111 MBq/L (3.0 mCi/mL) indium-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 (ferric ion, 1.2 μg/mL). The vial contents are sterile and nonpyrogenic. No bacteriological preservative is present.

In addition, the kit also contains the following items: (i) a 25 G x 5/8" needle (BD, Monoject) used to transfer Indium-111 Chloride Sterile Solution to the OctreoScan Reaction Vial; (ii) a pressure sensitive label; and (iii) a package insert.
Combining the high energies of Sopha and Summit

Sopha Medical and Summit Nuclear have merged to form a dynamic new company. As SMV, our combined forces are focused on being the finest nuclear medicine imaging company in the world.

Behind our new name stands a history rich in nuclear medicine firsts. In 1985 it was the first 32 bit computer. In 1991 the first variable angle camera. Not to mention advanced all-digital detectors and the most envied clinical software in the business. All of which resulted in new industry standards for quality, efficiency and value.

As SMV, our combination of powerful resources and strong financing, underscored by $50 million in committed capital, enables us to continue building on this tradition of excellence. To better meet the needs of our customers, SMV offers the most diverse product line-up in nuclear medicine. We offer solutions for meeting the vast array of clinical and economic requirements, and support them with comprehensive customer service.

Now, as you might expect from the world’s largest dedicated nuclear medicine company, the SMV commitment to research and development spans the globe. Our mission — discover new practical solutions which expand the clinical value and use of nuclear medicine. Assuring Sopha, Summit and SMV customers — currently numbering over 3,500 systems in 50 countries — a steady stream of enhancements to keep their investment right up with the cutting-edge for years to come.

If you are considering a new nuclear medicine imaging system, plug into the high energy of SMV. For more information on our dynamic new company, products and services, please contact:

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1993 Case Parkway
Twinsburg, Ohio 44087
1-800-664-0844

SMV International
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(33-1) 30-84-91-00

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NEW OPTiCEL™ DIGITAL DETECTORS. Sports cars aren’t the only high-performance machines that need constant tuning. To get optimal image quality consistently, your digital gammacamera will need ongoing adjustment as well. The question is, “Will you have to sacrifice uptime to get it?” Not with OptiCEL digital detectors from Toshiba. OptiCEL digital detectors feature Optotune™, an exclusive self-tuning technology that automatically adjusts the digital detector. That means that your Toshiba gammacamera will stay up and running, not up on the rack.

Available on Toshiba’s nuclear gammacamera systems, Optotune tunes the digital detector up to 512 times per second. That equates to super-crisp image quality every time, but of equal importance, it translates to exceptional reliability and maximum uptime. Digital detectors without Optotune may require service every two months to get similar tuning. And service time is downtime.

New OptiCEL digital detectors: powerful, self-tuned nuclear diagnostics designed to stay in service... and out of the shop. For more information call: 1-800-421-1968