Positron imaging is demonstrating improved outcomes for oncology. Reimbursement for certain applications is now approved—with the likelihood for more indications in the near future.

Successful integration of positron imaging into the clinical practice goes well beyond the delivery of a camera. It requires assistance in reimbursement, clinical protocols, radio-pharmaceuticals…and much more. That’s why Siemens offers total solutions for every aspect of PET and coincidence imaging. We make it easy to establish a quality positron imaging service.

Whether you perform a few positron procedures a month—or many each day—Siemens has specific product and service solutions to meet your every need. With the most extensive worldwide support network…and over 20 years of positron experience, we are well prepared to meet your individual challenges.

And when it comes to technology, there’s none better—for dedicated PET or coincidence imaging. See why Siemens ECAT® PET and E.CAM™ coincidence cameras are setting the standard in positron imaging today.
Siemens medical Solutions that help
The CAPTUS® 2000 brings PC-based, 1024-channel MCA power to your thyroid uptake and well counting needs. Accurate, fast, and easy-to-use menu-driven methods allow you to easily perform:

- Thyroid Uptakes
- Bioassay
- Wipe-tests (with automatic identification of nuclides)
- RBC Survival studies
- Dicopac® procedures
- Blood Volume measurements (with Cr-51 or I-125)
- Schilling Tests

Quality assurance is completely automatic with the included Cs-137 and Eu-152 check sources. The unit also comes standard with a roll-away stand for hassle-free operation... and the unique Spring-Arm Thyroid Probe positioner makes patient positioning a snap! Other configurations are available, too. Along with the roll-away stand, there are wall-mount and table top options which fit every need and budget.

Visit our web site at www.capintec.com or call us at 800-631-3826 (or 201-825-9500) to see which configuration is right for you!

Captus 2000:
Simple... Powerful... Everything you'd expect from CAPINTEC
Functional Anatomic Mapping

The first technology ever to combine the power of CT/PET and CT/SPECT in a single device. Available only from GE.
Before you spend another dime on a diagnostic imaging system, invest a minute in this ad.

Introducing Functional Anatomic Mapping—breakthrough diagnostic imaging technology that will, quite possibly, change the way you manage patients.

Never before has functional imaging been this precise, this exact. By combining the anatomical landmarks of CT with functional images, GE Medical Systems has created a new category of imaging that not only detects the presence of disease, but pinpoints its specific location. In fact, Functional Anatomic Mapping is the first technology ever to combine the power of CT/PET and CT/SPECT in a single device.

Through GE’s commitment to functional imaging and technological innovation, Functional Anatomic Mapping is a clinical reality. This diagnostic imaging breakthrough will be available worldwide on the Millennium VG system. Proof of the GE Continuum, our pledge to cost-effectively keep you at the forefront of technology.

To contact a GE representative, or for more information on Functional Anatomic Mapping, call 1-800-643-6439.

GE Medical Systems
We bring good things to life.
Quadramet® is indicated for the treatment of pain in patients with osteoblastic metastatic lesions that enhance on radionuclide bone scan. In clinical trials, this unique radiopharmaceutical has delivered measurable benefits in

**RESPONSE** Rapid onset of action—as soon as one week after administration.

**RELIEF** Effective and durable pain relief with reduced or eliminated need for opioids.

**RECOVERY** Generally mild and transient myelosuppression and predictable nadirs.

Your Berlex representative can show you how these benefits can support your cancer treatment strategies. Ask for information about the Quadramet® sampling program. 1-888-BERLEX4

Quadramet® causes myelosuppression. Prior to administration, clinical benefits should be judged to outweigh the risks in patients having compromised bone marrow reserves or undergoing other therapies that cause myelosuppression.

Please see brief summary of prescribing information following this advertisement.


Circle Reader Service No. 9
Brief Summary—Before Prescribing Call Toll Free Prescribing Information

INDICATIONS: Quadrant is indicated for relief of pain in patients with confirmed osteoblastic metastatic bone lesions that enhance on radionuclide bone scan.

CONTRAINDICATIONS: Quadrant is contraindicated in patients who have shown hypersensitivity to EDTMP or similar phosphonate compounds.

WARNINGS: Quadrant causes bone marrow suppression. In clinical trials, while blood cell counts and platelet counts decreased to a nadir of approximately 40% to 50% of baseline in 123 (95%) of patients within 3 to 5 weeks after Quadrant, and tended to return to pretreatment levels by 9 weeks. The grade of marrow toxicity is shown in Table 5 below.

Table 5

Number and percent of patients who experienced marrow toxicity in clinical trials of Quadrant

<table>
<thead>
<tr>
<th>Toxicity</th>
<th>Placebo</th>
<th>1.0 mcCi/kg</th>
<th>Placebo</th>
<th>1.0 mcCi/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade*</td>
<td>N = 85</td>
<td>N = 185</td>
<td>N = 85</td>
<td>N = 185</td>
</tr>
<tr>
<td>0-2</td>
<td>1.3%</td>
<td>12.6%</td>
<td>0.0%</td>
<td>10.5%</td>
</tr>
<tr>
<td>3</td>
<td>6.3%</td>
<td>20.1%</td>
<td>0.0%</td>
<td>13.0%</td>
</tr>
<tr>
<td>4</td>
<td>1.1%</td>
<td>20.1%</td>
<td>0.0%</td>
<td>6.0%</td>
</tr>
<tr>
<td>5</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>2.1%</td>
</tr>
</tbody>
</table>

Toxicity Grade based on National Cancer Institute criteria; normal levels are Hemoglobin >10 g/dL; Leucocyte >4.0 x 10^9/L, and Platelets >150,000/mcL.

Table 6

Selected adverse events reported in ≥ 1.0% of patients who received Quadrant or placebo in controlled clinical trials

<table>
<thead>
<tr>
<th>ADVERSE EVENT</th>
<th>Placebo</th>
<th>Quadrant 1.0 mcCi/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>N = 90</td>
<td>N = 90</td>
<td></td>
</tr>
<tr>
<td>Patients with Any Adverse Event</td>
<td>72 (80%)</td>
<td>169 (85%)</td>
</tr>
<tr>
<td>Body As A Whole</td>
<td>56 (62%)</td>
<td>100 (50%)</td>
</tr>
<tr>
<td>Pain Flair Reactions</td>
<td>5 (5.6%)</td>
<td>14 (7.0%)</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>19 (21%)</td>
<td>32 (16%)</td>
</tr>
<tr>
<td>Arthritic</td>
<td>2 (2.2%)</td>
<td>10 (5.0%)</td>
</tr>
<tr>
<td>Chest Pain</td>
<td>4 (4.4%)</td>
<td>8 (4.0%)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>0</td>
<td>6 (3.0%)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>2 (2.2%)</td>
<td>4 (2.2%)</td>
</tr>
<tr>
<td>Digestive</td>
<td>44 (49%)</td>
<td>82 (41%)</td>
</tr>
<tr>
<td>Abdominal Pain</td>
<td>7 (7.8%)</td>
<td>12 (6.0%)</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>3 (3.3%)</td>
<td>12 (6.0%)</td>
</tr>
<tr>
<td>Nausea / Vomiting</td>
<td>37 (41%)</td>
<td>65 (32.7%)</td>
</tr>
<tr>
<td>Hematologic &amp; Lytic</td>
<td>12 (13%)</td>
<td>54 (27%)</td>
</tr>
<tr>
<td>Coagulation Disorder</td>
<td>0</td>
<td>3 (1.5%)</td>
</tr>
<tr>
<td>Hemoglobin Decreased</td>
<td>21 (23.3%)</td>
<td>81 (40.7%)</td>
</tr>
<tr>
<td>Leukopenia</td>
<td>6 (6.7%)</td>
<td>119 (61.0%)</td>
</tr>
<tr>
<td>Lymphopenia</td>
<td>0</td>
<td>4 (2.0%)</td>
</tr>
<tr>
<td>Thrombocytopenia</td>
<td>8 (8.9%)</td>
<td>138 (69.3%)</td>
</tr>
<tr>
<td>Any Blood Malignations</td>
<td>8 (8.9%)</td>
<td>32 (16.5%)</td>
</tr>
<tr>
<td>Ectoderm</td>
<td>1 (1.1%)</td>
<td>3 (1.5%)</td>
</tr>
<tr>
<td>Epilepsia</td>
<td>1 (1.2%)</td>
<td>4 (2.2%)</td>
</tr>
<tr>
<td>Dermatosis</td>
<td>3 (3.3%)</td>
<td>16 (8.5%)</td>
</tr>
<tr>
<td>Infection</td>
<td>10 (11.1%)</td>
<td>34 (17.1%)</td>
</tr>
<tr>
<td>Fever and/or Chills</td>
<td>10 (11.1%)</td>
<td>17 (8.5%)</td>
</tr>
<tr>
<td>Infection NOS</td>
<td>4 (4.4%)</td>
<td>14 (7.0%)</td>
</tr>
<tr>
<td>Oral Malignias</td>
<td>1 (1.1%)</td>
<td>4 (2.2%)</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>1 (1.1%)</td>
<td>3 (1.5%)</td>
</tr>
<tr>
<td>Musculoskeletal</td>
<td>28 (31%)</td>
<td>55 (27%)</td>
</tr>
<tr>
<td>Myelodysplasia</td>
<td>8 (8.9%)</td>
<td>13 (6.5%)</td>
</tr>
<tr>
<td>Myelosuppression</td>
<td>2 (2.2%)</td>
<td>5 (2.5%)</td>
</tr>
<tr>
<td>Nervous</td>
<td>39 (44.9%)</td>
<td>59 (30.1%)</td>
</tr>
<tr>
<td>Bowel Distress</td>
<td>1 (1.1%)</td>
<td>8 (4.0%)</td>
</tr>
<tr>
<td>Paralysis</td>
<td>7 (7.8%)</td>
<td>4 (2.0%)</td>
</tr>
<tr>
<td>Spinal Cord Compression</td>
<td>5 (5.5%)</td>
<td>13 (6.5%)</td>
</tr>
<tr>
<td>Renal Failure</td>
<td>0</td>
<td>2 (1.0%)</td>
</tr>
<tr>
<td>Respiratory</td>
<td>24 (27%)</td>
<td>35 (18%)</td>
</tr>
<tr>
<td>Bronchitis/Thoracic Infection</td>
<td>2 (2.2%)</td>
<td>8 (4.0%)</td>
</tr>
<tr>
<td>Skin Lesions</td>
<td>11 (12%)</td>
<td>11 (6.0%)</td>
</tr>
<tr>
<td>Skin Infections</td>
<td>17 (19%)</td>
<td>13 (7.0%)</td>
</tr>
<tr>
<td>Pulmonary</td>
<td>0</td>
<td>2 (1.0%)</td>
</tr>
<tr>
<td>Rashes</td>
<td>2 (2.2%)</td>
<td>2 (1.0%)</td>
</tr>
</tbody>
</table>

In an additional 200 patients who received Quadrant in uncontrolled clinical trials, adverse events that were reported at a rate of ≥ 1% were similar for 9 (45%) patients who had agranulocytosis. Other adverse events that were reported in <1% of the patients who received Quadrant 1.0 mcCi/kg in any clinical trial include akinesia, angina, congestive heart failure, sinus bradycardia, and vasodilation.

OVERDOSE: Overdose with Quadrant has not been reported. An antidote for Quadrant overdose is not known. The anticipated complications of overdose would likely be secondary to bone marrow suppression from the radioactivity of 153Sm, or secondary to hypocalcemia and cardiac arrhythmias related to the EDTMP.

DOSAGE AND ADMINISTRATION: The recommended dose of Quadrant is 1.0 mcCi/kg, administered intravenously over a period of one minute through a secure in-dwelling catheter and followed with a saline flush. Dose adjustment in patients at the extremes of weight have not been studied. Caution should be exercised when determining the dose in very thin or very obese patients.

The dose should be measured by a suitable radioactivity calibration system, such as a radiospectro dose calibrator, immediately before administration.

The dose should be administered in the patient and should be verified before administration. Quadrant should not be released until their radioactivity levels and exposure rates comply with federal and local regulations.

The patient should ingest (or receive by intravenous administration) a minimum of 500 mL (2 cups) of fluids prior to injection and should void as often as possible after injection to minimize radiation exposure to the bladder.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. The solution should not be used if it is cloudy or if it contains particulate matter. Quadrant contains calcium and may be incompatible with solutions that contain materials that can complex with calcium precipitates.

Quadrant should not be diluted or mixed with other solutions.

How to administer Quadrant: Quadrant is administered by the intravenous route immediately after dilution with 1000 mL of sterile water for injection. The solution should be used within 8 hours of thawing.

BERLEX Laboratories, Inc.
It's hard to believe this vial contains something so small it is actually big enough to change the way we diagnose and treat diseases. Yet the radioisotopes used in nuclear medicine are an integral part of patient care. The many applications for nuclear medicine imaging are having a dramatic impact on early diagnosis and staging of illnesses including heart disease and cancer.

MDS Nordion is one of the world's leading producers of radioisotopes—a role we're proud of, and an obligation we take very seriously. That's why we are forging ahead with a significant investment by building two new reactors, MAPLE 1 and 2, dedicated to medical radioisotope production.

Backed by 50 years' experience, MDS Nordion offers its customers superior quality, reliable distribution, 24-hour customer service and specialized expertise.
Upon Suspicion of Pulmonary Malignancy

NeoTect, a noninvasive nuclear imaging agent, characterizes pulmonary masses as being rich in somatostatin receptors.¹,²

- Many malignant pulmonary masses and some inflammatory processes overexpress somatostatin receptors (SSTRs)¹
- For use in patients who are known to have or are highly suspect for malignancy and have pulmonary lesions on CT and/or chest x-ray.¹

The clinical benefit of NeoTect as a population-based screening tool has not been studied. NeoTect is not an alternative to CT or biopsy.¹

NeoTect, like other small peptides, may induce hypersensitivity reactions or anaphylactic reactions. Adequate treatment provisions, including epinephrine, should be available for immediate use.¹

Please see brief summary of prescribing information on following page.

¹ 2000 Berlex Laboratories and Nycomed Amersham
NeoFect™

Kit for the Preparation of Technetium Tc 99m Deproteid Injection

Brief Summary of Prescribing Information

DESCRIPTION

NeoFect™ (Kit for the Preparation of Technetium Tc 99m Deproteid Injection) is intended for use in the preparation of Technetium Tc 99m Deproteid, a diagnostic radiopharmaceutical to be used by intravenous injection. Each vial contains a sterile, non-pyrogenic lyophilized mixture of 50 μg of Deproteid, 5 mg of sodium glucophosphate dihydrate, 50 μg of atenolol chloride dihydrate (with a minimum stannous ion content of 15 μg). 100 μg eseretic diiodide dihydrate, and sufficient sodium hydroxide or hydrochloric acid for adjustment to pH 7.4 prior to lyophilization. The lyophilized powder is sealed under a nitrogen atmosphere with a rubber closure. The product contains no antimicrobial preservative.

When sterile, non-pyrogenic Sodium Pertechnetate Tc 99m Injection, in 0.9% Sodium Chloride Injection, U.S.P. is added to the vial, a Technetium Tc 99m complex of Deproteid is formed.

INDICATIONS AND USAGE

NeoFect™ is a scintigraphic imaging agent that identifies somatostatin receptor-bearing pulmonary masses in patients presenting with pulmonary lesions on computed tomography and/or chest x-ray who have known malignancy or who are highly suspect for malignancy.

CONTRAINDICATIONS

None known.

WARNINGS

None.

PRECAUTIONS

General

Therapy with somatostatin analogues can produce severe hypoglycemia in patients with insulinomas. Since Deproteid binds to somatostatin receptors, caution should be exercised when administering this drug to patients with insulinomas. NeoFect™ as other small peptides, may induce hypersensitivity reactions or anaphylactic reactions. Adequate treatment provisions, including epiephrine, should be available for immediate use. In preliminary studies of 18 subjects, NeoFect™ did not produce increases in IGG or IGM production 3 weeks following injection. Other immune parameters such as eosinophils, other immunoglobulins, complement, lymphokines or cytokines were not studied.

Technetium Tc 99m Deproteid Injection, like other radioactive drugs, must be handled with care and appropriate safety measures should be used to minimize radiation exposure to clinical personnel. Care should also be taken to minimize radiation exposure to the patient consistent with proper patient management.

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

Urinary excretion of radioactivity occurs primarily during the first 4 hours following injection. Studies have not been done to determine the amount of radioactivity that might be eliminated in the feces. (See Clinical Pharmacology Section.) Special precautions should be taken with incompetent patients to minimize the risk of radioactive contamination of clothing, bed linen, and the patient’s environment.

Information For Patients

To minimize radiation absorbed dose to the bladder, adequate hydration should be encouraged to permit frequent voiding during the first few hours after injection of NeoFect™. This may be achieved by having patients drink at least 8 oz. glass of water prior to drug administration. To help protect themselves and others in their environment, patients should take the following precautions for 12 hours after injection: whenever possible a toilet should be used and should be flushed several times after each use and patients should wash their hands thoroughly after each voiding or urination. If blood, urine or feces soil the clothing, the clothing should be washed separately.

Laboratory Tests

There was a low incidence (1% or less) of transient and clinically insignificant changes in serine aminotransferase (ALT), white blood cell count, and eosinophil count following administration of Technetium Tc 99m Deproteid Injection.

Drug Interactions

Drug interactions were not noted in clinical studies in which Technetium Tc 99m Deproteid Injection was administered to patients receiving concomitant medication.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Studies have not been conducted to evaluate carcinogenic potential or effects on fertility. The results of the following genotoxicity studies with decayed Technetium Tc 99m Deproteid Injection or with deproteid were negative. Salmonella/Escherichia coli reverse mutation assay, in vitro mouse lymphoma assay with and without metabolic activation, and in vivo mouse micronucleus assay.

Pregnancy

Pregnancy Category C. Animal reproduction studies have not been conducted with decayed Technetium Tc 99m Deproteid Injection. It is not known whether Technetium Tc 99m Deproteid Injection can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Technetium Tc 99m Deproteid Injection should be given to a pregnant woman only if clearly needed. Studies in pregnant women have not been conducted.

Nursing Mothers

Studies have not been conducted with deproteid to determine its excretion in human milk. Technetium Tc 99m Pertechnetate is excreted in human milk. It is not known whether Technetium Tc 99m Deproteid Injection is excreted in human milk. Caution should be exercised when Technetium Tc 99m Deproteid Injection is administered to a nursing woman. Wherever possible, infant formula should be substituted for breast milk until the technetium has been eliminated.

Pediatric Use

Safety and effectiveness of Deproteid in pediatric patients below the age of 16 years have not been established.

ADVERSE REACTIONS

Adverse events were evaluated in clinical studies of 647 adults who received 15.0 to 20.0 mCi Technetium Tc 99m labeled to approximately 50 μg of Deproteid. Of these adults, 56% were men and 44% women. The mean age was 59.0 years (18-86 years).

Deaths did not occur during the clinical study period. After Technetium Tc 99m Deproteid Injection, serious adverse events were not reported. At least one adverse event occurred in 29/647 (4.5%) patients after Technetium Tc 99m Deproteid Injection. Headache was the most commonly reported adverse event (1% of patients). Table 8 lists adverse events reported in ≥ 0.5% or more of patients who received Technetium Tc 99m Deproteid Injection.

<table>
<thead>
<tr>
<th>Table 8</th>
<th>ADVERSE EVENTS REPORTED IN ≥ 0.5% OF PATIENTS FOLLOWING NEOFECT™ INJECTION IN CLINICAL TRIALS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Patients Exposed</td>
<td>647</td>
</tr>
<tr>
<td>Number of Patients with At Least One Adverse Event</td>
<td>29 (4.5%)</td>
</tr>
<tr>
<td>Nervous System</td>
<td>12 (1.9%)</td>
</tr>
<tr>
<td>Headache</td>
<td>7 (1.1%)</td>
</tr>
<tr>
<td>Dizziness</td>
<td>5 (0.8%)</td>
</tr>
<tr>
<td>Gastronomic System</td>
<td>7 (1.1%)</td>
</tr>
<tr>
<td>Nausea</td>
<td>3 (0.5%)</td>
</tr>
<tr>
<td>Vascular (extracardiac) Disorder</td>
<td>3 (0.5%)</td>
</tr>
<tr>
<td>Rash</td>
<td>2 (0.3%)</td>
</tr>
</tbody>
</table>

Other adverse events which occurred in ≥ 0.5% of patients following administration of NeoFect™ included: arteriosclerosis, back pain, chest pain, diarrhea, fatigue, gait abnormality, glosotaxis, hypoaesthesia, infection, leg cramps, lymphocytosis, malaise, pharyngitis, somnolence, taste perversion.

DOSEAGE AND ADMINISTRATION

For imaging, NeoFect™ is administered as a peripheral intravenous injection at a single dose of 15 to 20 mCi containing approximately 50 μg of Technetium Tc 99m radiolabeled Deproteid peptide. Patients should drink at least an 8 oz. glass of water before drug administration. The contents of kit for the Preparation of Technetium Tc 99m Deproteid Injection are intended only for use in the preparation of Technetium Tc 99m Deproteid Injection and are not to be administered directly to the patient. Only the labeled dose should be drawn from each reconstituted vial. (See Instructions for the Preparation Section.)

The potential need for dose adjustment has not been studied in patients with renal insufficiency, or in pediatric or geriatric patients, or in patients on therapeutic somatostatin analogues.

IMAGING

Planar and SPECT images of the chest should be obtained between 2-4 hours after NeoFect™ administration. SPECT images of the chest are required for optimal image interpretation.

RADIATION DOSIMETRY

Based on the data, the absorbed radiation dose to an average human adult (70 kg) from an intravenous injection of the agent is listed in Table 9. The values are listed in descending order as rad/mCi and mGy/MBq and assume urinary bladder emptying at 4.8 hours.

<table>
<thead>
<tr>
<th>Table 9</th>
<th>Estimated Absorbed Radiation Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target Organ</td>
<td>rad/mCi</td>
</tr>
<tr>
<td>Kidneys</td>
<td>0.33</td>
</tr>
<tr>
<td>Spleen</td>
<td>0.16</td>
</tr>
<tr>
<td>Testes</td>
<td>0.12</td>
</tr>
<tr>
<td>Thyroid Gland</td>
<td>0.098</td>
</tr>
<tr>
<td>Red Marrow</td>
<td>0.078</td>
</tr>
<tr>
<td>Liver</td>
<td>0.078</td>
</tr>
<tr>
<td>Heart wall</td>
<td>0.064</td>
</tr>
<tr>
<td>Bone surface</td>
<td>0.054</td>
</tr>
<tr>
<td>Lungs</td>
<td>0.053</td>
</tr>
<tr>
<td>Adrenal gland</td>
<td>0.044</td>
</tr>
<tr>
<td>Pancreas</td>
<td>0.037</td>
</tr>
<tr>
<td>Urinary bladder</td>
<td>0.033</td>
</tr>
<tr>
<td>Uterus</td>
<td>0.031</td>
</tr>
<tr>
<td>Small Intestine</td>
<td>0.019</td>
</tr>
<tr>
<td>Upper Large Intestine</td>
<td>0.019</td>
</tr>
<tr>
<td>Overas</td>
<td>0.018</td>
</tr>
<tr>
<td>Lower Large Intestine</td>
<td>0.014</td>
</tr>
</tbody>
</table>

Dose calculations were performed using the standard MIRD method (MIRD Pamphlet No. 1 rev., Soc. Nucl. Med., 1978). Effective dose equivalent was calculated in accordance with ICRP 53 (Ann. ICRP 18, 1. 4, 1988) and gave a value of 0.032 mSv/MBq (0.94 rad/mCi). HOW SUPPLIED

Each kit is comprised of one vial containing a sterile, non-pyrogenic, freeze-dried mixture of Deproteid, stannous chloride dihydrate, sodium glucophosphate dihydrate and edetate disodium dihydrate. Kits are available as individual vials or as packs of five.

NDC 04570-511-10 - single vial
NDC 04570-511-05 - five vial pack

STORAGE
Store the kit at < -10 °C (≤ 14 °F). Store the reconstituted injection solution at 20-25 °C (68-77 °F) using appropriate radiation shielding. Use within 5 hours of reconstitution.

The kit should be protected from light.

Distributed by:
Diastec, Inc.
9 Delta Drive
Longonderry, New Hampshire 03053

Revised August 1989


EXPANDING YOUR VISION

Circle Reader Service No. 135

40-4300000708A

BERLEX
Exercise and pharmacologic stress testing should be performed only under the supervision of a qualified physician. Cardiolite® has been rarely associated with acute severe allergic events of angioedema and urticaria. The most frequently reported adverse events include headache, chest pain/angina, ST segment changes on ECG, nausea, and abnormal taste and smell.

©2000 DuPont Pharmaceuticals Company
INDICATIONS AND USAGE: Myocardial Imaging: CARDIOLITE®. Kit for the Preparation of Technetium Tc99m Sestamibi for Injection, is a pharmacologic imaging agent that is indicated for detecting coronary artery disease by localizing myocardial ischemia (see Warnings and Precautions). It is not to be used to diagnose myocardial infarction or to differentiate a recent myocardial infarction from ischemia.

Breast Imaging: MIRALUMA™. Kit for the Preparation of Technetium Tc99m Sestamibi for Injection, is a pharmacologic imaging agent that is indicated for evaluating cancerous lesions in patients with abnormal mammograms or palpable breast masses.

MIRALUMA™ is not indicated for breast cancer screening, to confirm the presence or absence of malignancy, or as an alternative to biopsy.

CONTRAINDICATIONS: None known.

WARNINGS: In studying patients in whom cardiac disease is known or suspected, care should be taken to ensure the safety and treatment in patients with severe, acute, or uncontrolled angina. In such patients, death has occurred 4 to 24 hours after Thoriem administration and is usually associated with exercise testing (see PRECAUTIONS).

Radioactive drugs must be handled with care and appropriate safety measures should be used to minimize radiation exposure to the patient and personnel. The patient should be told before administration that the test involves an injection of a radioactive material.

Sodium Sestamibi, when used with care, is non-pyrogenic and is designed for diagnostic imaging. The components of the kit are sterile and nonpyrogenic. It is essential to follow directions carefully and to adhere to appropriate precautions during preparation.

MIRALUMA™ is not indicated for breast cancer screening, to confirm the presence or absence of malignancy, or as an alternative to biopsy.

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 further dilution and reconstitution (see Warnings). The diluent and reconstitution are included in the kit. Radioactive drugs must be handled with care and appropriate safety measures should be used to minimize radiation exposure to the patient and personnel. The patient should be told before administration that the test involves an injection of a radioactive material.

Sodium Sestamibi, when used with care, is non-pyrogenic and is designed for diagnostic imaging. The components of the kit are sterile and nonpyrogenic. It is essential to follow directions carefully and to adhere to appropriate precautions during preparation.

MIRALUMA™ is not indicated for breast cancer screening, to confirm the presence or absence of malignancy, or as an alternative to biopsy.

STRESS

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

- Fatigue (35%)
- Dyspnea (15%)
- Chest Pain (15%)
- ST-depression (7%)
- Arthralgia (1%)

Information for Patients: CARDIOLITE® and MIRALUMA™ are different names for the same drug.

Patients should be advised to inform their health care provider if they had any allergic reaction to either drug or if they had an imaging study with either drug.

Cardiotoxicity: Impairment of Fertility: In comparison with most other diagnostic technetium-labeled radiopharmaceuticals, the radiation dose to the ovaries (1.2 rad/30 mCi at rest, 1.3 rad/30 mCi at exercise) is high. Minimum exposure (ALARA) is necessary in women of childbearing capability. (See Dosimetry subsection in DOSAGE AND ADMINISTRATION section.)

The active intermediate, [Ga(III)], was evaluated for genotoxic potential in a battery of five tests. No genotoxic activity was observed in the Ames, CHO/PSTP and sister chromatid exchange tests (all in vitro). At cytotoxic concentrations (200 µM), an increase in cells with chromosome aberrations was observed in the CHO cell line. However, [Ga(III)], did not show genotoxic effects in the in vivo mouse micronucleus test at a dose which caused systemic and bone marrow toxicity (8 mg/kg, >90% in a maximal human dose).

Hematopoetic and reproductive toxicities has not been conducted with Technetium Tc99m Sestamibi. It is not known whether Technetium Tc99m Sestamibi can cause fetal harm when administered to pregnant women or if it 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.

NURSE WARNING: 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 feeding.

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

ADVERSE REACTIONS: Adverse events were evaluated in 3714 adults who were evaluated in clinical studies. Of these patients, 3068 (82% men, 22% women, and 0.7% of the patient's genders were not recorded) were in cardiac clinical trials and 672 (100% women) in breast imaging trials. Cases of angina, chest pain, and death were observed (see Warnings and Precautions). Adverse events reported at a rate of 0.5% or greater. Before receiving Technetium Tc99m Sestamibi administration are shown in the following table:

Table: Table 6. Adverse Events Reported At A Rate Of 0.5% Or Clinical Studies*  
<table>
<thead>
<tr>
<th>Body System</th>
<th>Women</th>
<th>Men</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>N = 672</td>
<td>N = 3068</td>
<td>N = 3068</td>
<td>N = 3068</td>
</tr>
<tr>
<td>Body as a Whole</td>
<td>1 (0.1%)</td>
<td>1 (0.0%)</td>
<td>1 (0.0%)</td>
</tr>
<tr>
<td>Headache</td>
<td>1 (0.1%)</td>
<td>1 (0.0%)</td>
<td>1 (0.0%)</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>1 (0.1%)</td>
<td>0 (0.0%)</td>
<td>1 (0.0%)</td>
</tr>
<tr>
<td>Diabetic Events</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Headache</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Hypersensitivity</td>
<td>1 (0.1%)</td>
<td>1 (0.0%)</td>
<td>1 (0.0%)</td>
</tr>
<tr>
<td>Hypothermia</td>
<td>1 (0.1%)</td>
<td>1 (0.0%)</td>
<td>1 (0.0%)</td>
</tr>
<tr>
<td>Skin Disorders</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Special Sens</td>
<td>1 (0.1%)</td>
<td>0 (0.0%)</td>
<td>1 (0.0%)</td>
</tr>
<tr>
<td>Urinary Infections</td>
<td>1 (0.1%)</td>
<td>1 (0.0%)</td>
<td>1 (0.0%)</td>
</tr>
</tbody>
</table>

Phenobarbital 25 patients whose genders were not reported. In the clinical studies for breast imaging, breast pain was reported in 12 (1.7%) of 11. In 11 of these patients the pain appears to be associated with biopsy/surgical procedures.

Dosage and Administration for Myocardial Imaging: The suggested dose range for I.V. administration of CARDIOLITE® in a single dose is 20 to 110 mCi (0.74 to 4.0 MBq) for patients 70 kg or greater. For patients weighing less than 70 kg, the dose should be reduced by 10 mCi (0.37 MBq) for each 10 kg less than 70 kg. For the correct dose calculation, see Table 1. CARDIOLITE® evaluation of myocardial ischemia can be accomplished with rest and cardiovascular stress techniques (e.g., exercise or pharmacologic stress in accordance with accepted stress agent for each patient). It is usually not possible to determine the age of a myocardial infarction from a single injection of Technetium Tc99m Sestamibi. In the rare patients in whom acute coronary ischemia was not apparent. Pharmacologic imaging and Sestamibi. In the rare patients in whom acute coronary ischemia was not apparent.

MIRALUMA™ is not indicated for breast cancer screening, to confirm the presence or absence of malignancy, or as an alternative to biopsy.

The doped injection of Technetium Tc99m Sestamibi is expressed in terms of 110 MBq (3 mCi) of Technetium Tc99m Sestamibi injected intravenously are shown in Table 10.

Radiation Dose: The radiation dose from the use of Technetium Tc99m Sestamibi for Therapeutic use is shown in Table 1. For the correct dose calculation, see Table 1. The radiation dose from the use of Technetium Tc99m Sestamibi for Therapeutic use is shown in Table 1.
PERFECT HIP REPLACEMENT.

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AcuTect offers a greater measure of confidence, clearly imaging even the most difficult-to-find iliac clots

As the first imaging modality to target acute DVT, AcuTect increases your ability to detect dangerous clots in those patients with signs and symptoms — even in the most difficult patient types. Whether the patient is obese, has a suspected deep iliac clot, is immobile or in a cast or other contraindications, AcuTect finds its target — binding preferentially to the glycoprotein (GP) IIb/IIIa receptors found on activated platelets. AcuTect is specific to the acute disease process — not just the anatomical obstruction. Its state-of-the-art peptide technology offers a choice when other modalities may not measure up to detecting an actively forming acute DVT.

Clinical follow-up studies of patients with negative AcuTect scans have not been performed to determine if negative image findings mean the absence of acute venous thrombosis. If a patient has clinical signs and symptoms of acute venous thrombosis, a clinical management decision to withhold treatment with anticoagulants should not be based on a negative AcuTect study alone.

After administration of AcuTect, as with the administration of other intravenous drugs, patients with a history of drug reactions, other allergies, or immune system disorders should be observed for several hours.

The difference is acute.

AcuTect (kit for the Preparation of Technetium Tc 99m Apocidine Injection)
ADVERSE REACTIONS

Adverse events were evaluated in clinical studies of 642 adults who received technetium Tc 99m 20.0 μCi labeled to approximately 10-125 μg of bisiblocast. Of these adults, 48% were women and 52% men. The mean age was 57.0 years (17 to 95 years). In all patients, adverse events were monitored for at least 3 hours. A subset of 189 patients, adverse events were monitored for 24 hours. Deaths did not occur during the clinical study period. Following injection of technetium Tc 99m aptidole, a serious episode of hypotension occurred in one patient who had acute hypertension that began within 10 minutes of injection and, over 60 minutes, progressed to a systolic pressure of 70 mm Hg.

At least one adverse event occurred in 29/642 (4.5%) of patients after technetium Tc 99m aptidole injection. Pain was the most commonly reported adverse event (1.7% of patients or healthy volunteers). Table 1 lists adverse events reported in 0.5% or more of patients who received technetium Tc 99m aptidole.

<table>
<thead>
<tr>
<th>Table 1: ADVERSE EVENTS IN patients WHO HAVE RECEIVED ACUTECT® INJECTION IN CLINICAL STUDIES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Patients Exposed to ACUTECT®</td>
</tr>
<tr>
<td>Number of Patients with At Least One Adverse Event</td>
</tr>
<tr>
<td>Body As a Whole</td>
</tr>
<tr>
<td>Pain (back, leg, chest)</td>
</tr>
<tr>
<td>Headache</td>
</tr>
<tr>
<td>Cardiovascular System</td>
</tr>
<tr>
<td>Hypertension</td>
</tr>
<tr>
<td>Hypertension</td>
</tr>
</tbody>
</table>

Other adverse events which occurred in <0.5% of patients following receipt of ACUTECT® included: agitation, asthma, bradycardia, cardiovascular disorder, chills, convulsions, dizziness, fever, hypertension, injection site reaction, liver enzyme elevation, nausea, paresthesia, pruritus, sweat, tachycardia, twitch, urticaria, and vomiting.

OVERDOSAGE: Clinical consequences of overdosing with technetium Tc 99m aptidole have not been studied.

DOSAGE AND ADMINISTRATION: To detect acute venous thrombosis in a lower extremity, reconstructed AcuTect® should be administered as a peripheral intravenous injection in an upper extremity, at a dose of approximately 100 μg of bisibloc radiolabeled with 20 μCi of technetium Tc 99m.

Technetium Tc 99m aptidole should be drawn into the syringe and administered using sterile technique. If nondisposable equipment is used, ampoules should be discarded immediately after use to prevent residual contamination with traces of cleansing agents. Unused portions of the drug must be discarded appropriately. (See Instructions for Preparation Section of Full Product Information.)

Lower Extremity Imaging

AcuTect® imaging should begin between 10 and 60 minutes after injection. Patients should void just before imaging in order to limit the influence of urinary bladder radioactivity since technetium Tc 99m aptidole is cleared from the blood by the kidney. It is important to note that imaging needs to be repeated, additional images may be obtained up to 180 minutes without re-injection. The safety of more than one dose has not been studied.

Positive AcuTect® uptake in the deep venous structures is defined as asymmetric vascular uptake (with or without superimposed diffuse uptake) in contrast enhanced images, and asymmetry in both anterior and posterior projections. If asymmetry appears only after extreme contrast enhancement, then diffuse asymmetry must also be present for an image to score as an image positive.

Superficial increased uptake is not to be interpreted as acute deep venous thrombosis.

RADIATION DOSIMETRY

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

<table>
<thead>
<tr>
<th>Table 2: Radiation Absorbed Doses for a 70kg Adult</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target Organ</td>
</tr>
<tr>
<td>Urinary Bladder Wall</td>
</tr>
<tr>
<td>Kidneys</td>
</tr>
<tr>
<td>Lower Large Intestine Wall</td>
</tr>
<tr>
<td>Upper Large Intestine Wall</td>
</tr>
<tr>
<td>Testes/Ovaries</td>
</tr>
<tr>
<td>Lung</td>
</tr>
<tr>
<td>Red Marrow</td>
</tr>
<tr>
<td>Breast</td>
</tr>
</tbody>
</table>

Dose calculations were performed using the standard MIRD method (MIRD Pamphlet No. 1, Rev. Soc. Nucl. Med., 1978). Effective dose equivalent was calculated in accordance with ICRP 53 (Ann. ICRP 18. 1-4. 1988) and gave a value of 0.0003 rad/mCi or 0.0004 mSv/mCi.

HOW SUPPLIED

Each kit contains one vial containing a sterile, nonpyrogenic, freeze-dried mixture of bisiblocast, stannous chloride dihydrate and sodium glutamate dihydrate, together with a package insert and adverse event reporting cards. Kits are available in packs of 5 vials.

Storage

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

The kit should be protected from light.

Rx only

Diatidex, Inc. Rev. September 1998
9 Delta Drive, Londonderry, New Hampshire 03053
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06401-980-A

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References

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In studying patients with known or suspected coronary artery disease, care should be taken to ensure continuous cardiac monitoring and the availability of emergency cardiac treatment.
Pediatric Use
Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS
Adverse events were evaluated in clinical trials of 764 adults (511 men and 253 women) with a mean age of 58.7 years (range 29-94 years). The subjects received a mean dose of 7.67 mCi on the first injection and 22.4 mCi on the second injection of Myoview™.

Deaths did not occur during the clinical study period of 2 days. Six cardiac deaths occurred 3 days to 6 months after injection and were thought to be related to the underlying disease or cardiac surgery. After Myoview injection, serious episodes of angina occurred in 3 patients. Overall cardiac adverse events occurred in 5/764 (less than 1%) of patients after Myoview injection.

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

- Cardiac: angina, hypertension, Torsades de Pointes
- Gastrointestinal: vomiting, abdominal discomfort
- Hypersensitivity: cutaneous allergy, hypotension, dyspnea
- Other: allergic reaction, burning, diaphoresis

There was a low incidence (less than 4%) of a transient and clinically insignificant rise in white blood cell counts following administration of the agent.

DOSE AND ADMINISTRATION

For exercise and rest Imaging, Myoview is administered in two doses:

The first dose of 5-6 mCi (185-296 MBq) is given at peak exercise.

The second dose of 15-24 mCi (555-888 MBq) is given approximately 4 hours later, at rest. Imaging may begin 15 minutes following administration of the agent.

Dose adjustment has not been established in renal or liver impaired, pediatric or geriatric patients.

RADIATION DOSIMETRY

Based on human data, the absorbed radiation doses to an average human adult (70 kg) from intravenous injections of the agent under exercise and resting conditions are listed in the following table. The values are listed in descending order as rad/mCi and µGy/MCi and assume urinary bladder emptying at 3.5 hours.

Estimated Absorbed Radiation Dose (Technetium Tc99m Tetrofosmin Injection)

<table>
<thead>
<tr>
<th>Target organ</th>
<th>Exercise</th>
<th>Rest</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gall bladder wall</td>
<td>0.123</td>
<td>0.180</td>
</tr>
<tr>
<td>Liver</td>
<td>0.075</td>
<td>0.113</td>
</tr>
<tr>
<td>Bladder wall</td>
<td>0.068</td>
<td>0.071</td>
</tr>
<tr>
<td>Lower large intestine</td>
<td>0.057</td>
<td>0.082</td>
</tr>
<tr>
<td>Small intestine</td>
<td>0.045</td>
<td>0.063</td>
</tr>
<tr>
<td>Kidney</td>
<td>0.039</td>
<td>0.046</td>
</tr>
<tr>
<td>Salivary glands</td>
<td>0.030</td>
<td>0.043</td>
</tr>
<tr>
<td>Uterus</td>
<td>0.027</td>
<td>0.035</td>
</tr>
<tr>
<td>Bone surface</td>
<td>0.023</td>
<td>0.021</td>
</tr>
<tr>
<td>Pancreas</td>
<td>0.019</td>
<td>0.020</td>
</tr>
<tr>
<td>Stomach</td>
<td>0.017</td>
<td>0.017</td>
</tr>
<tr>
<td>Thymus</td>
<td>0.016</td>
<td>0.022</td>
</tr>
<tr>
<td>Adrenals</td>
<td>0.016</td>
<td>0.021</td>
</tr>
<tr>
<td>Heart wall</td>
<td>0.015</td>
<td>0.015</td>
</tr>
<tr>
<td>Rad marrow</td>
<td>0.015</td>
<td>0.015</td>
</tr>
<tr>
<td>Spleen</td>
<td>0.015</td>
<td>0.014</td>
</tr>
<tr>
<td>Muscle</td>
<td>0.013</td>
<td>0.032</td>
</tr>
<tr>
<td>Testes</td>
<td>0.013</td>
<td>0.011</td>
</tr>
<tr>
<td>Liver</td>
<td>0.012</td>
<td>0.022</td>
</tr>
<tr>
<td>Thymus</td>
<td>0.012</td>
<td>0.009</td>
</tr>
<tr>
<td>Brain</td>
<td>0.010</td>
<td>0.008</td>
</tr>
<tr>
<td>Lungs</td>
<td>0.008</td>
<td>0.007</td>
</tr>
<tr>
<td>Skin</td>
<td>0.006</td>
<td>0.007</td>
</tr>
<tr>
<td>Breast</td>
<td>0.006</td>
<td>0.007</td>
</tr>
</tbody>
</table>

**MRN**

Dose calculations were performed using the standard MIRD method (MIRD Pamphlet No 1, rev. Society of Nuclear Medicine, 1978). Effective dose equivalents (EDE) were calculated in accordance with ICRP 53 (Ann. ICRP 18 (1-4), 1988) and gave values of 0.81 x 10^-2 milliSv/mCi and 1.12 x 10^-2 milliSv/mCi after exercise and rest, respectively.

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MIRD Head and Brain Dosimetry
Lionel G. Bouchet, Wesley E. Bolch, Barry W. Wessels, David Weber & the SNM MIRD Committee
ISBN 0-932004-70-9
This text provides the absorbed fractions of energy and absorbed dose per unit cumulated activity within pediatric and adult head and brain models for use in nuclear medicine internal dosimetry. Six models covering ages from birth to adult are described. Comprehensive tables of absorbed fractions and S values for all models and radiopharmaceuticals are presented and include steps for verifying these calculations and tabulations.
Price: $50 (members); $70 (non-members)

MIRD Supplement to The Journal of Nuclear Medicine 1999
Don't miss your opportunity to have the latest dosimetry models in one volume. A compilation of MIRD Pamphlets Numbers 14 (revised) through 17. This important collection of recent MIRD pamphlets covers urinary bladder model for radiation dose calculations (revised from 1992), radionuclide S values in a revised dosimetric model of the adult head and brain, quantitative radiopharmaceutical biodistribution data acquisition and analysis, and the dosimetry of nonuniform activity distributions.
Price: $30 (members); $42 (non-members)

MIRD Cellular S Values
S. Murty Goddu, Roger W. Howell, Lionel G. Bouchet, Wesley E. Bolch, Dandamudi Rao & the SNM MIRD Committee
ISBN 0-932004-46-6
This reference provides the necessary tools to estimate the absorbed dose at the cellular level from intracellularly localized radionuclides using cellular S values for emitters of monoenergetic electrons and alpha particles, and radionuclides listed in Radionuclide Data and Decay Schemes. Cellular absorbed-dose estimates play an important role in evaluating the relative merits of different radionuclides and radiopharmaceuticals in improving the overall safety and efficacy of diagnostic and therapeutic nuclear medicine.
Price: $45 (members); $63 (non-members)

MIRD Primer for Absorbed Dose Calculations (revised edition)
Robert Loewinger, Thomas F. Budinger & Evelyn E. Watson
The MIRD Primer is unquestionably the standard reference on absorbed dosage of radiopharmaceuticals in human beings, offering a thorough review of absorbed dose calculations used in the application of radiopharmaceuticals to medical studies. Included are detailed explanations of MIRD schema, examples of the application of the schema, dose estimates and technical appendices.
Price: $35 (members); $49 (non-members)

MIRD Radionuclide Data and Decay Schemes
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