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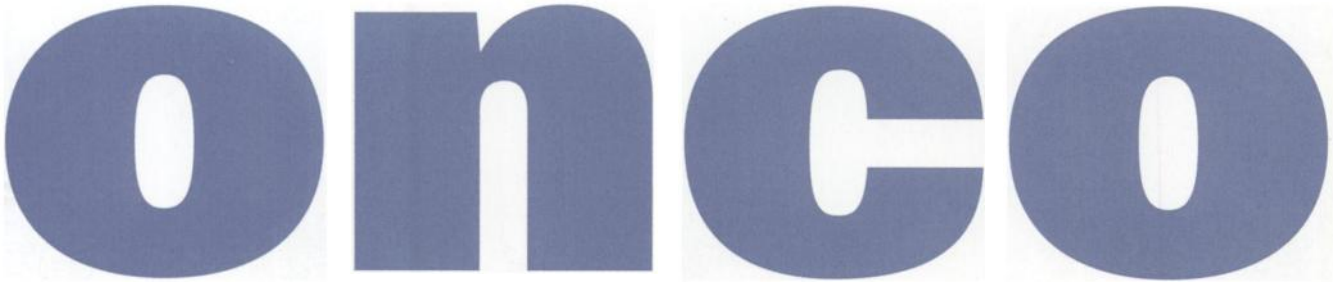

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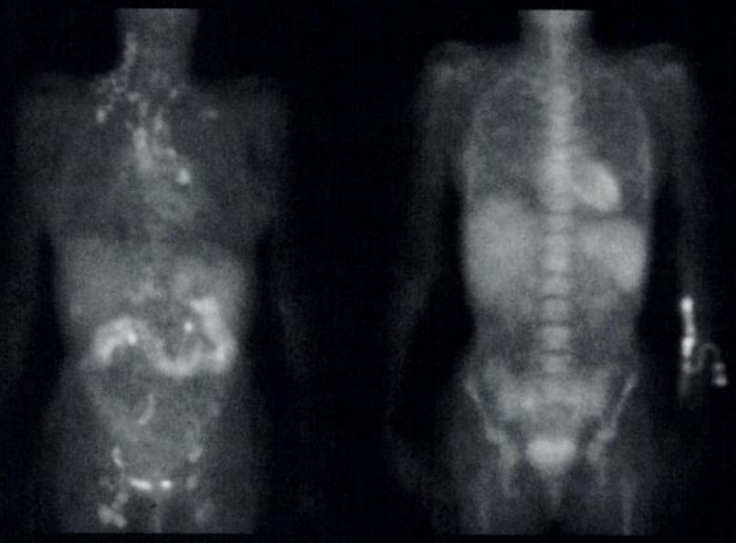

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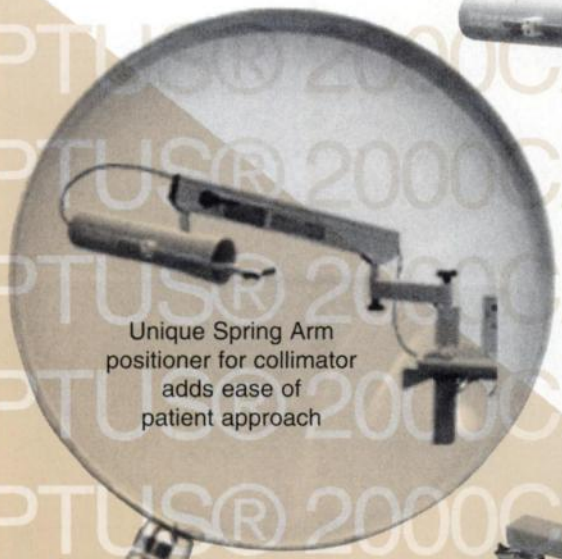

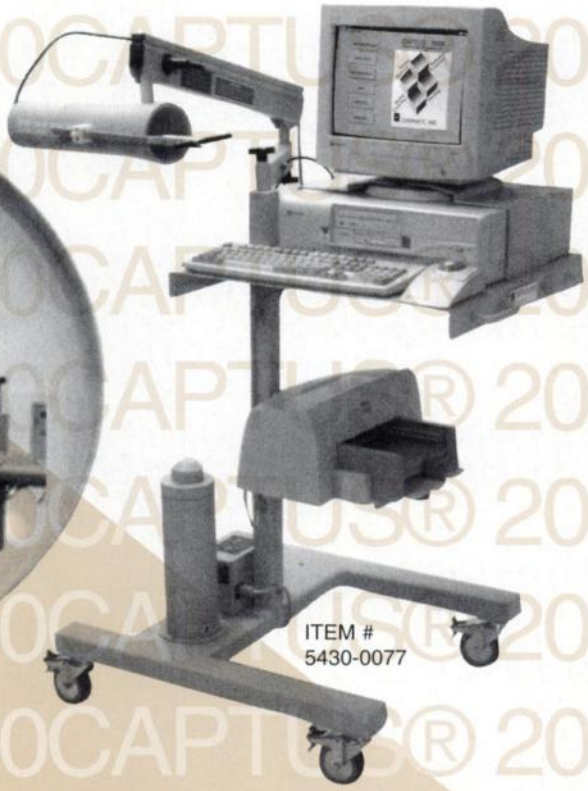

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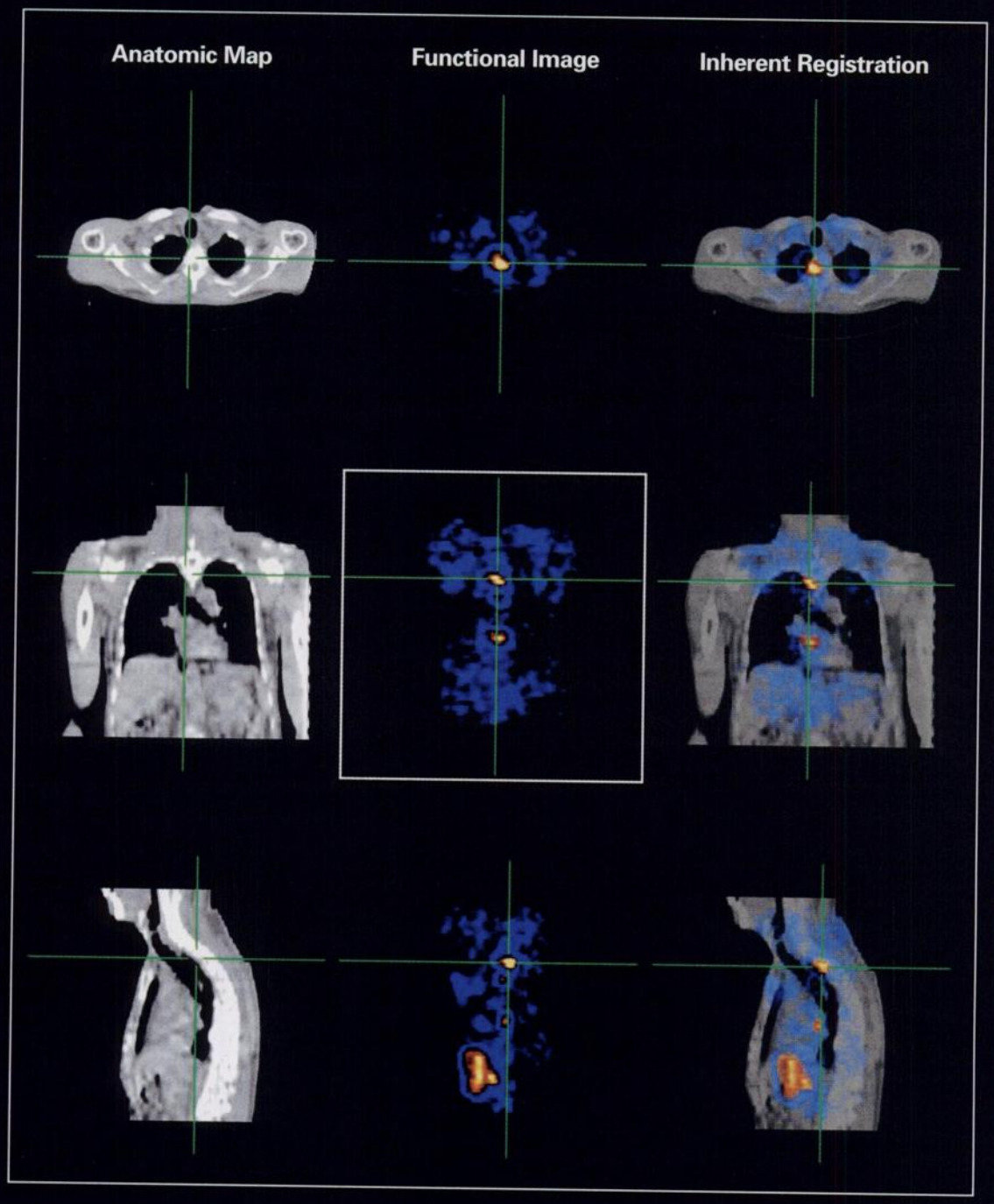

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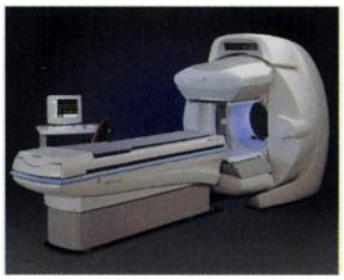

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RESPONSE Rapid onset of action—as soon as one week after administration.[1]

RELIEF Effective and durable pain relief with reduced or eliminated need for opioids.[2]

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AT FIRST SIGHT

QUADRAMET®

(SAMARIUM SM-153 LEXIDRONAM INJECTION)

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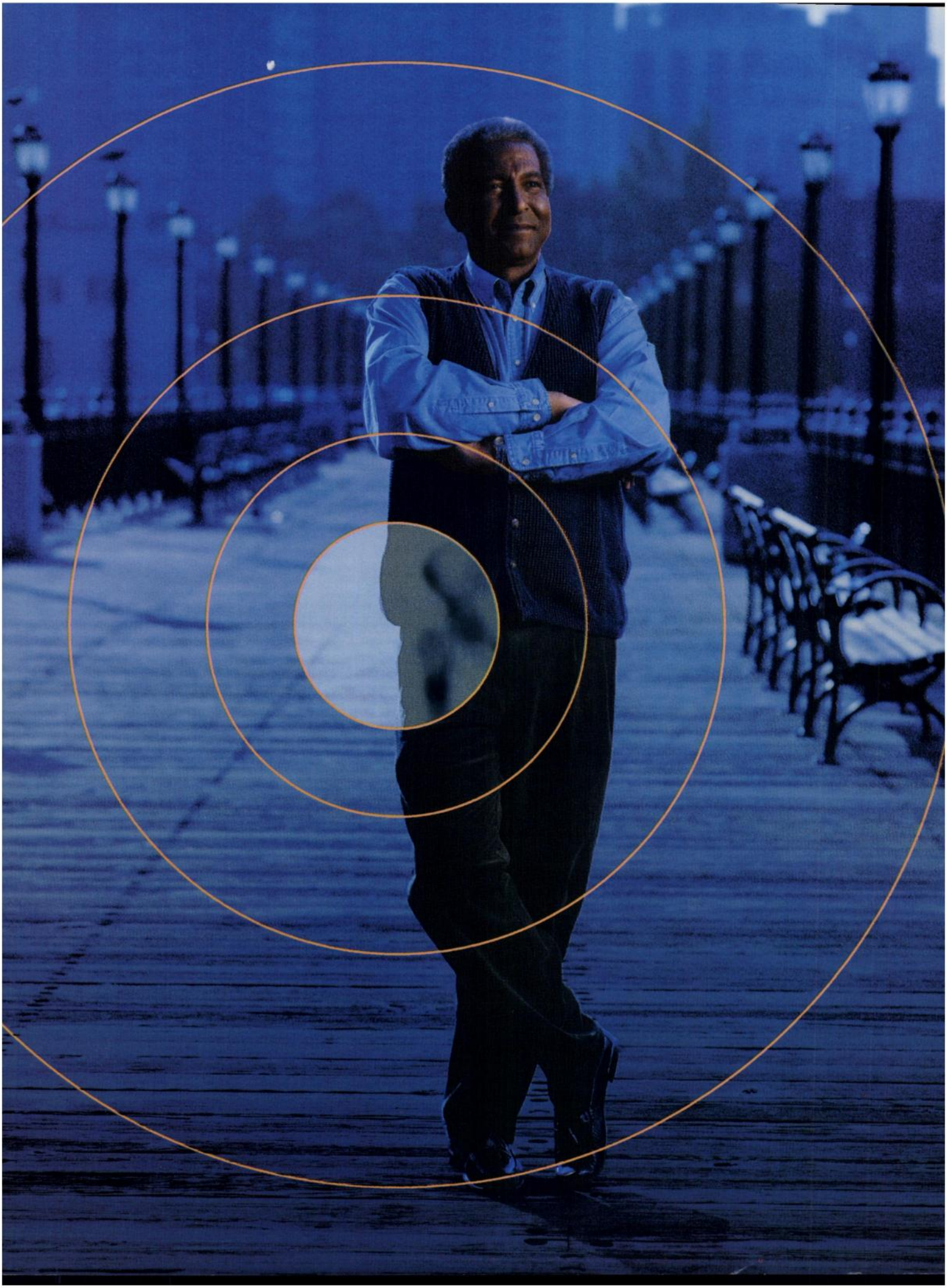
Quadramet® causes myelosuppression. Prior to administration, clinical benefits should be judged to outweigh the risks in patients having compromised bone marrow reserves or undergoing other therapies that cause myelosuppression.

Please see brief summary of prescribing information following this advertisement.

1. Quadramet® prescribing information. 2. Serafini AN, Houston SJ, Resche I, et al. Palliation of pain associated with metastatic bone cancer using samarium-153 lexidronam: a double-blind placebo-controlled clinical trial. *J Clin Oncol.* 1998;16:1574–1581.



QUADRAMET.
(SAMARIUM SM-153 LEXIDRONAM INJECTION)

BERLEX®
Laboratories, Inc.

Brief Summary—Before Prescribing Consult Full Prescribing Information

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

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

WARNINGS: Quadramet causes bone marrow suppression. In clinical trials, white 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 Quadramet, and tended to return to pretreatment levels by 8 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 Quadramet

	Hemoglobin		Leucocytes		Platelets	
Toxicity Grade*	Placebo N = 85	1.0 mCi/kg N = 185	Placebo N = 85	1.0 mCi/kg N = 184	Placebo N = 85	1.0 mCi/kg N = 185
0–2	78 (92%)	162 (88%)	85 (100%)	169 (92%)	85 (100%)	173 (94%)
3	6 (7%)	20 (11%)	0 (0%)	15 (8%)	0 (0%)	10 (5%)
4	1 (1%)	3 (2%)	0 (0%)	0 (0%)	0 (0%)	2 (1%)

Toxicity Grade based upon National Cancer Institute Criteria; normal levels are Hemoglobin >10g/dL, Leucocyte ≥4.0 x 10³/μL, and Platelets ≥150,000/μL.

Before Quadramet is administered, consideration should be given to the patient's current clinical and hematologic status and bone marrow response history to treatment with myelotoxic agents. Metastatic prostate and other cancers can be associated with disseminated intravascular coagulation (DIC); caution should be exercised in treating cancer patients whose platelet counts are falling or who have other clinical or laboratory findings suggesting DIC. Because of the unknown potential for additive effects on bone marrow, Quadramet should not be given concurrently with chemotherapy or external beam radiation therapy unless the clinical benefits outweigh the risks. Use of Quadramet in patients with evidence of compromised bone marrow reserve from previous therapy or disease involvement is not recommended unless the potential benefits of the treatment outweigh the risks. Blood counts should be monitored weekly for at least 8 weeks, or until recovery of adequate bone marrow function.

Pregnancy: As with other radiopharmaceutical drugs, Quadramet can cause fetal harm when administered to a pregnant woman. Adequate and well controlled studies have not been conducted in animals or pregnant women. Women of childbearing age should have a negative pregnancy test before administration of Quadramet. If this drug is used during pregnancy, or if a patient becomes pregnant after taking this drug, the patient should be apprised of the potential hazard to the fetus. Women of child-bearing potential should be advised to avoid becoming pregnant. Men and women patients should be advised to use an effective method of contraception after the administration of Quadramet.

PRECAUTIONS: EDTMP is a chelating agent. Although the chelating effects have not been evaluated thoroughly in humans, dogs that received non-radioactive samarium EDTMP (6 times the human dose based on body weight, 3 times based on surface area) developed a variety of electrocardiographic (ECG) changes (with or without the presence of hypocalcemia). The causal relationship between the hypocalcemia and ECG changes has not been studied. Whether Quadramet causes electrocardiographic changes or arrhythmias in humans has not been studied. Caution and appropriate monitoring should be given when administering Quadramet to patients (See Laboratory Tests).

Because concomitant hydration is recommended to promote the urinary excretion of Quadramet, appropriate monitoring and consideration of additional supportive treatment should be used in patients with a history of congestive heart failure or renal insufficiency.

This drug should be used with caution in patients with compromised bone marrow reserves. See Warnings.

Skeletal: Spinal cord compression frequently occurs in patients with known metastases to the cervical, thoracic or lumbar spine. In clinical studies of Quadramet, spinal cord compression was reported in 7% of patients who received placebo and in 8.3% of patients who received 1.0 mCi/kg Quadramet. Quadramet is not indicated for treatment of spinal cord compression. Quadramet administration for pain relief of metastatic bone cancer does not prevent the development of spinal cord compression. When there is a clinical suspicion of spinal cord compression, appropriate diagnostic and therapeutic measures must be taken immediately to avoid permanent disability.

Radiopharmaceutical agents 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 authorized to license the use of radionuclides.

Quadramet, like other radioactive drugs, must be handled with care, and appropriate safety measures must be taken to minimize radiation exposure of clinical personnel and others in the patient environment.

Special precautions, such as bladder catheterization, should be taken with incontinent patients to minimize the risk of radioactive contamination of clothing, bed linen, and the patient's environment. Urinary excretion of radioactivity occurs over about 12 hours (with 35% occurring during the first 6 hours). Studies have not been done on the use of Quadramet in patients with renal impairment.

PREGNANCY: Pregnancy Category D. See Warnings Section.

NURSING MOTHERS: It is not known whether Quadramet is excreted in human milk. Because of the potential for serious adverse reactions in nursing infants from Quadramet, a decision should be made whether to continue nursing or to administer the drug. If Quadramet is administered, formula feedings should be substituted for breast feedings.

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

ADVERSE EVENTS: Adverse events were evaluated in a total of 580 patients who received Quadramet in clinical trials. Of the 580 patients, there were 472 men and 108 women with a mean age of 66 (range 20 to 87).

Of these patients, 472 (83%) had at least one adverse event. In a subgroup of 399 patients who received Quadramet 1.0 mCi/kg, there were 23 deaths and 46 serious adverse events. The deaths occurred an average of 67 days (9 to 130) after Quadramet. Serious events occurred an average of 46 days (1 - 118) after Quadramet. Although most of the patient deaths and serious adverse events appear to be related to the underlying disease, the relationship of end stage disease, marrow invasion by cancer cells, previous myelotoxic treatment and Quadramet toxicity can not be easily distinguished. In clinical studies, two patients with rapidly progressive prostate cancer developed thrombocytopenia and died 4 weeks after receiving Quadramet. One of the patients showed evidence of disseminated intravascular coagulation (DIC); the other patient experienced a fatal cerebrovascular accident, with a suspicion of DIC. The relationship of the DIC to the bone marrow suppressive effect of Samarium is not known. Marrow toxicity occurred in 277 (47%) patients (See Warnings section).

In controlled studies, 7% of patients receiving 1.0 mCi/kg Quadramet (as compared to 6% of patients receiving placebo) reported a transient increase in bone pain shortly after injection (flare reaction). This was usually mild, self-limiting, and responded to analgesics.

The most common adverse events observed in controlled clinical studies of Quadramet, are given in Table 6 below.

Table 6

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

ADVERSE EVENT	Placebo N = 90	Quadramet 1.0 mCi/kg N = 199
# Patients with Any Adverse Event	72 (80%)	169 (85%)
Body As A Whole	56 (62%)	100 (50%)
Pain Flare Reaction	5 (5.6%)	14 (7.0%)
Cardiovascular	19 (21%)	32 (16%)
Arrhythmias	2 (2.2%)	10 (5.0%)
Chest Pain	4 (4.4%)	8 (4.0%)
Hypertension	0	6 (3.0%)
Hypotension	2 (2.2%)	4 (2.0%)
Digestive	44 (49%)	82 (41%)
Abdominal Pain	7 (7.8%)	12 (6.0%)
Diarrhea	3 (3.3%)	12 (6.0%)
Nausea &/or Vomiting	37 (41.1%)	65 (32.7%)
Hematologic & Lymphatic	12 (13%)	54 (27%)
Coagulation Disorder	0	3 (1.5%)
Hemoglobin Decreased	21 (23.3%)	81 (40.7%)
Leukopenia	6 (6.7%)	118 (59.3%)
Lymphadenopathy	0	4 (2.0%)
Thrombocytopenia	8 (8.9%)	138 (69.3%)
Any Bleeding Manifestations	8 (8.9%)	32 (16.1%)
Ecchymosis	1 (1.1%)	3 (3.0%)
Epistaxis	1 (1.1%)	4 (2.0%)
Hematuria	3 (3.3%)	10 (5%)
Infection	10 (11.1%)	34 (17.1%)
Fever and/or Chills	10 (11.1%)	17 (8.5%)
Infection NOS	4 (4.4%)	14 (7.0%)
Oral Moniliasis	1 (1.1%)	4 (2.0%)
Pneumonia	1 (1.1%)	3 (1.5%)
Musculoskeletal	28 (31%)	55 (27%)
Myasthenia	8 (8.9%)	13 (6.5%)
Pathologic Fracture	2 (2.2%)	5 (2.5%)
Nervous	39 (43%)	59 (30%)
Dizziness	1 (1.1%)	8 (4.0%)
Paresthesia	7 (7.8%)	4 (2.0%)
Spinal Cord Compression	5 (5.5%)	13 (6.5%)
Cerebrovascular Accident/Stroke	0	2 (1.0%)
Respiratory	24 (27%)	35 (18%)
Bronchitis/Cough Increased	2 (2.2%)	8 (4.0%)
Special Senses	11 (12%)	11 (6%)
Skin & Appendages	17 (19%)	13 (7%)
Purpura	0	2 (1%)
Rash	2 (2.2%)	2 (1%)

Includes hemorrhage (gastrointestinal, ocular) reported in <1%.

In an additional 200 patients who received Quadramet in uncontrolled clinical trials, adverse events that were reported at a rate of ≥1.0% were similar except for 9 (4.5%) patients who had agranulocytosis. Other adverse events that were reported in <1% of the patients who received Quadramet 1.0 mCi/kg in any clinical trial include: alopecia, angina, congestive heart failure, sinus bradycardia, and vasodilation.

OVERDOSAGE: Overdosage with Quadramet has not been reported. An antidote for Quadramet overdosage is not known. The anticipated complications of overdosage would likely be secondary to bone marrow suppression from the radioactivity of ^{153}Sm, or secondary to hypocalcemia and cardiac arrhythmias related to the EDTMP.

DOSAGE AND ADMINISTRATION: The recommended dose of Quadramet is 1.0 mCi/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 radioisotope dose calibrator, immediately before administration.

The radioactive dose to be administered and the patient should be verified before administering Quadramet. Patients should not be released until their radioactivity levels and exposure rates comply with federal and local regulations.

The patient should ingest (or receive by i.v. 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.

Quadramet contains calcium and may be incompatible with solutions that contain molecules that can complex with and form calcium precipitates.

Quadramet should not be diluted or mixed with other solutions.

Thaw at room temperature before administration and use within 8 hours of thawing.

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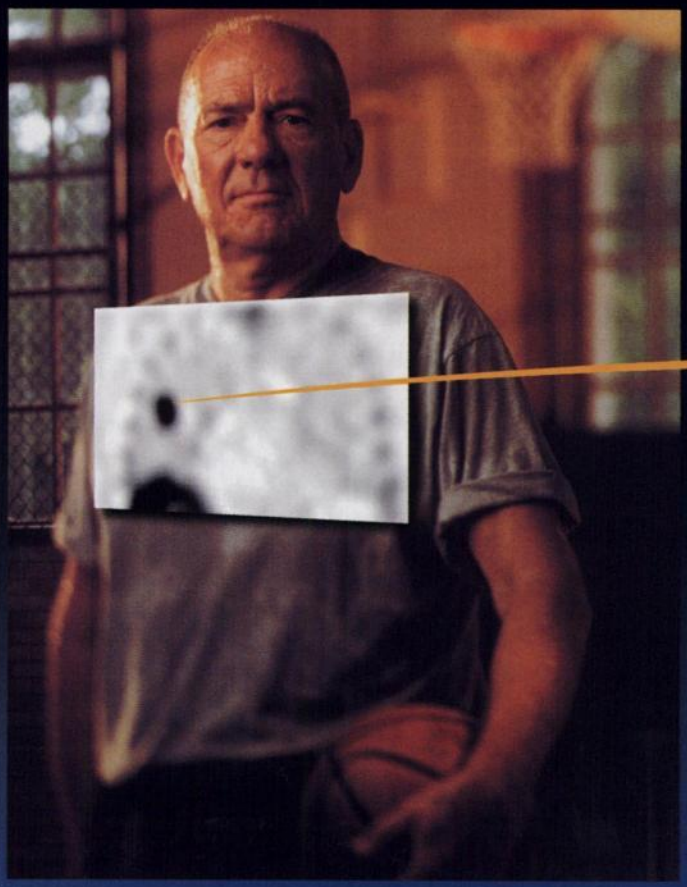
Upon Suspicion of Pulmonary Malignancy



NeoTect™

Kit for the Preparation of Technetium Tc 99m Depreotide Injection

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Noninvasively Characterizes Pulmonary Masses

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]

Normal SPECT image

Positive SPECT image, malignancy confirmed by histology (adenocarcinoma)

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.

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NeoTect™

Kit for the Preparation of Technetium Tc 99m Depreotide Injection

Brief Summary of Prescribing Information

DESCRIPTION

NeoTect™ (Kit for the Preparation of Technetium Tc 99m Depreotide Injection) is intended for use in the preparation of Technetium Tc 99m Depreotide, a diagnostic radiopharmaceutical to be used by intravenous injection. Each vial contains a sterile, non-pyrogenic lyophilized mixture of 50 µg of Depreotide, 5 mg of sodium glucoheptonate dihydrate, 50 µg of stannous chloride dihydrate (with a minimum stannous tin content of 15 µg), 100 µg edetate disodium 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 Depreotide is formed.

INDICATIONS AND USAGE

NeoTect™ 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 Depreotide binds to somatostatin receptors, caution should be exercised when administering this drug to patients with insulinomas.

NeoTect™, as other small peptides, may induce hypersensitivity reactions or anaphylactic reactions. Adequate treatment provisions, including epinephrine, should be available for immediate use. In preliminary studies of 18 subjects, NeoTect™ 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 Depreotide 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.

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

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 incontinent 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 NeoTect™. This may be achieved by having patients drink at least an 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 fecal elimination. 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 alanine aminotransferase (ALT), white blood cell count, and eosinophil count following administration of Technetium Tc 99m Depreotide Injection.

Drug Interaction

Drug interactions were not noted in clinical studies in which Technetium Tc 99m Depreotide 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 Depreotide Injection or with depreotide 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 Depreotide Injection. It is not known whether Technetium Tc 99m Depreotide Injection can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Technetium Tc 99m Depreotide 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 depreotide to determine its excretion in human milk. Technetium Tc 99m Pertechnetate is excreted in human milk. It is not known whether Technetium Tc 99m Depreotide Injection is excreted in human milk. Caution should be exercised when Technetium Tc 99m Depreotide 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 Depreotide 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 depreotide. Of these adults, 58% were men and 42% women. The mean age was 59.0 years (18-86 years).

Deaths did not occur during the clinical study period. After Technetium Tc 99m Depreotide Injection, serious adverse events were not reported.

At least one adverse event occurred in 29/647 (4.5 %) patients after Technetium Tc 99m Depreotide 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 Depreotide Injection.

TABLE 8
ADVERSE EVENTS REPORTED IN ≥ 0.5% OF PATIENTS FOLLOWING NeoTect™ INJECTION IN CLINICAL TRIALS

Number of Patients Exposed	647
Number of Patients with At Least One Adverse Event	29 (4.5%)
Nervous System	13 (2%)
Headache	7 (1.0%)
Dizziness	5 (0.8%)
Gastrointestinal System	7 (1.0%)
Nausea	4 (0.6%)
Vascular (extracardiac) Disorder	3 (0.5%)
Flushing	3 (0.5%)

Other adverse events which occurred in < 0.5% of patients following administration of NeoTect™ included: arthrosis, back pain, chest pain, diarrhea, fatigue, gait abnormality, glossitis, hemoptysis, hypoaesthesia, infection, leg cramps, lymphocytosis, malaise, pharyngitis, somnolence, taste perversion.

DOSAGE AND ADMINISTRATION

For imaging, NeoTect™ 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 Depreotide 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 Depreotide Injection are intended only for use in the preparation of Technetium Tc 99m Depreotide Injection and are not to be administered directly to the patient. Only one patient 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 NeoTect™ administration. SPECT images of the chest are required for optimal image interpretation.

RADIATION DOSIMETRY

Based on human data, the absorbed radiation dose to an average human adult (70 kg) from an intravenous injection of the agent are 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 9 Estimated Absorbed Radiation Dose

Target Organ	rad/mCi	mGy/MBq
Kidneys	0.33	0.090
Spleen	0.16	0.042
Testes	0.11	0.031
Thyroid Gland	0.088	0.024
Red Marrow	0.078	0.021
Liver	0.078	0.021
Heart wall	0.054	0.014
Bone surface	0.054	0.015
Lungs	0.053	0.014
Adrenal glands	0.044	0.012
Pancreas	0.037	0.010
Urinary bladder	0.033	0.0089
Uterus	0.031	0.0084
Small Intestine	0.019	0.0050
Upper Large Intestine	0.019	0.0050
Ovaries	0.016	0.0042
Lower Large Intestine	0.014	0.0038

Dose calculations were performed using the standard MIRD method (MIRD Pamphlet No. 1 rev., Soc. Nucl. Med., 1976). Effective dose equivalent was calculated in accordance with ICRP 53 (Ann. ICRP 18, 1-4, 1988) and gave a value of 0.023 mSv/MBq (0.084 rem/mCi).

HOW SUPPLIED

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

NDC 64570-511-10 - single vial

NDC 64570-511-05 - 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.

Rx Only

Distributed by:

Diatide, Inc.
9 Delta Drive
Londonderry, New Hampshire 03053
Revised August 1999

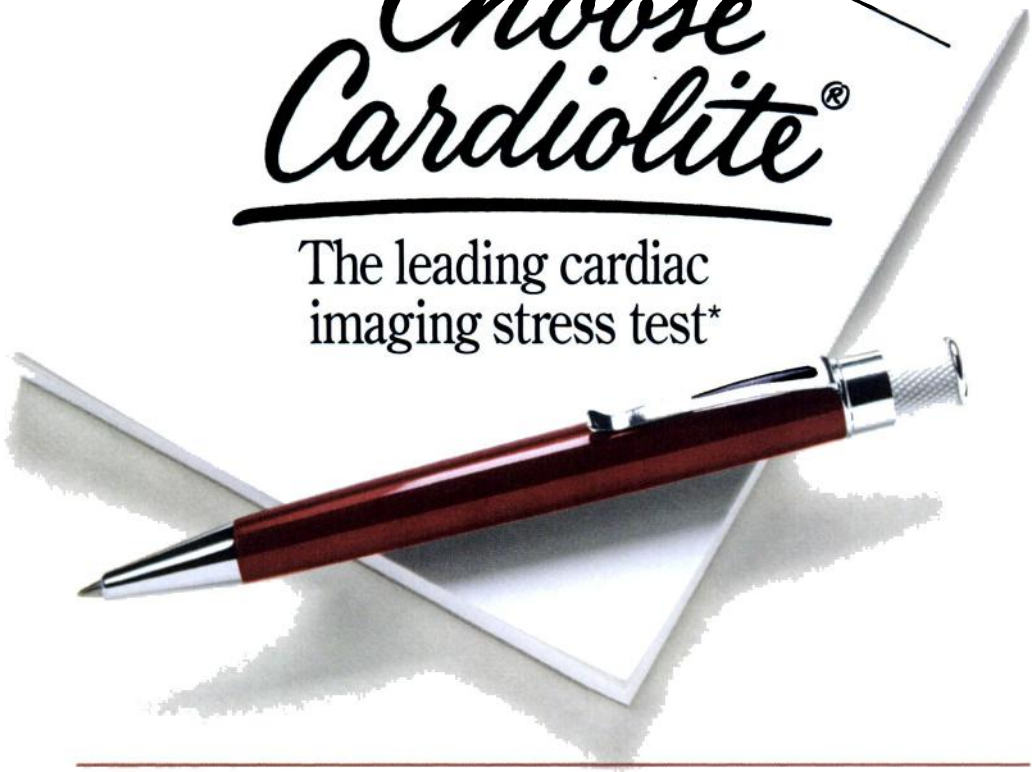
References: 1. NeoTect™ Prescribing Information. 2. Blum JE, Handmaker H, Rinne NA. The utility of a somatostatin-type receptor binding peptide radiopharmaceutical (P829) in the evaluation of solitary pulmonary nodules. *Chest.* 1999;115:224-232.

FOR CONFIDENCE IN MAKING CLINICAL DECISIONS

℞

Choose Cardiolite®

The leading cardiac imaging stress test*



Thank you for making Cardiolite® #1

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.

H52585

Brief Summary

Cardiolite®

Kit for the Preparation of Technetium Tc99m Sestamibi for Injection

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

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

Breast Imaging: MIRALUMA™, Kit for the Preparation of Technetium Tc99m Sestamibi for Injection, is indicated for planar imaging as a second line diagnostic drug after mammography to assist in the evaluation of breast lesions in patients with an abnormal mammogram or a palpable breast mass.

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

CONTRAINDICATIONS: None known.

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

Pharmacologic induction of cardiovascular stress may be associated with serious adverse events such as myocardial infarction, arrhythmia, hypotension, bronchoconstriction and cerebrovascular events. Caution should be used when pharmacologic stress is selected as an alternative to exercise; it should be used when indicated and in accordance with the pharmacologic stress agent's labeling.

Technetium Tc99m Sestamibi has been rarely associated with acute severe allergic and anaphylactic events of angioedema and generalized urticaria. In some patients the allergic symptoms developed on the second injection during CARDIOLITE® imaging. Patients who receive CARDIOLITE® or MIRALUMA™ imaging are receiving the same drug. Caution should be exercised and emergency equipment should be available when administering Technetium Tc99m Sestamibi. Also, before administerings either CARDIOLITE® or MIRALUMA™, patients should be asked about the possibility of allergic reactions to either drug.

PRECAUTIONS:

GENERAL

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

Radioactive 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 not 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. It is essential to follow directions carefully and to adhere to strict aseptic procedures during preparation.

Technetium Tc99m labeling reactions involved 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.

Radiopharmaceuticals 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 authorized to license the use of radionuclides.

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

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

Fatigue	35%
Dyspnea	17%
Chest Pain	16%
ST-depression	7%
Arrhythmia	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.

Carcinogenesis, Mutagenesis, Impairment of Fertility: In comparison with most other diagnostic technetium-labeled radiopharmaceuticals, the radiation dose to the ovaries (1.5 rads/30 mCi at rest, 1.2 rads/30 mCi at exercise) is high. Minimal exposure (ALARA) is necessary in women of childbearing capability. (See Dosimetry subsection in DOSAGE AND ADMINISTRATION section.)

The active intermediate, $[Cu(MIBI)_4]BF_4$, was evaluated for genotoxic potential in a battery of five tests. No genotoxic activity was observed in the Ames, CHO/HPRT and sister chromatid exchange tests (all in vitro). At cytotoxic concentrations (≥20 µg/ml), an increase in cells with chromosome aberrations was observed in the in vitro human lymphocyte assay. $[Cu(MIBI)_4]BF_4$ did not show genotoxic effects in the in vivo mouse micronucleus test at a dose which caused systemic and bone marrow toxicity (9 mg/kg, > 600 x maximal human dose).

Pregnancy Category C: Animal reproduction and teratogenicity 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 Pertechnetate is excreted in human milk during lactation. It is not known whether Technetium Tc99m Sestamibi is excreted in human milk. Therefore, formula feedings should be substituted for breast feedings.

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

ADVERSE REACTIONS: Adverse events were evaluated in 3741 adults who were evaluated in clinical studies. Of these patients, 3068 (77% men, 22% women, and 0.7% of the patient's genders were not recorded) were in cardiac clinical trials and 673 (100% women) in breast imaging trials. Cases of angina, chest pain, and death have occurred (see Warnings and Precautions). Adverse events reported at a rate of 0.5% or greater after receiving Technetium Tc99m Sestamibi administration are shown in the following table:

Table 9. Selected Adverse Events Reported in > 0.5% of Patients Who Received Technetium Tc99m Sestamibi in Either Breast Or Cardiac Clinical Studies*

Body System	Breast Studies	Cardiac Studies		
	Women N = 673	Women N = 685	Men N = 2361	Total N = 3046
Body as a Whole	21 (3.1%)	6 (0.9%)	17 (0.7%)	23 (0.8%)
Headache	11 (1.6%)	2 (0.3%)	4 (0.2%)	6 (0.2%)
Cardiovascular	9 (1.3%)	24 (3.5%)	75 (3.2%)	99 (3.3%)
Chest Pain/Angina	0 (0%)	18 (2.6%)	46 (1.9%)	64 (2.1%)
ST segment changes	0 (0%)	11 (1.6%)	29 (1.2%)	40 (1.3%)
Digestive System	8 (1.2%)	4 (0.6%)	9 (0.4%)	13 (0.4%)
Nausea	4 (0.6%)	1 (0.1%)	2 (0.1%)	3 (0.1%)
Special Senses	132 (19.6%)	62 (9.1%)	160 (6.8%)	222 (7.3%)
Taste Perversion	129 (19.2%)	60 (8.8%)	157 (6.6%)	217 (7.1%)
Parosmia	8 (1.2%)	6 (0.9%)	10 (0.4%)	16 (0.5%)

*Excludes the 22 patients whose genders were not recorded.

In the clinical studies for breast imaging, breast pain was reported in 12 (1.7%) of the patients. In 11 of these patients the pain appears to be associated with biopsy/surgical procedures.

The following adverse reactions have been reported in < 0.5% of patients: signs and symptoms consistent with seizure occurring shortly after administration of the agent; transient arthritis; angioedema, arrythmia, dizziness, syncope, abdominal pain, vomiting, and severe hypersensitivity characterized by dyspnea, hypotension, bradycardia, asthenia, and vomiting within two hours after a second injection of Technetium Tc99m Sestamibi. A few cases of flushing, edema, injection site inflammation, dry mouth, fever, pruritis, rash, urticaria and fatigue have also been attributed to administration of the agent.

DOSAGE AND ADMINISTRATION: For Myocardial Imaging: The suggested dose range for I.V. administration of CARDIOLITE® in a single dose to be employed in the average patient (70 Kg) is 370-1110 MBq (10-30 mCi).

For Breast Imaging: The recommended dose range for I.V. administration of MIRALUMA™ is a single dose of 740-1110 MBq (20 – 30 mCi).

Image Acquisition: Breast Imaging: It is recommended that images are obtained with a table overlay to separate breast tissue from the myocardium and liver, and to exclude potential activity that may be present in the opposite breast. For lateral images, position the patient prone with the isolateral arm comfortably above the head, shoulders flat against the table, head turned to the side and relaxed, with the breast imaged pendent through an overlay cutout. The breast should not be compressed on the overlay. For anterior images, position the patient supine with both arms behind the head. For either lateral or anterior images, shield the chest and abdominal organs, or remove them from the field of view.

For complete study, sets of images should be obtained five minutes after the injection, and in the following sequence:

Beginning five minutes after the injection of Technetium Tc99m Sestamibi:

- ten-minute lateral image of breast with abnormality
- ten-minute lateral image of contralateral breast
- ten-minute anterior image of both breasts

RADIATION DOSIMETRY: The radiation doses to organs and tissues of an average patient (70 kg) per 1110 MBq (30 mCi) of Technetium Tc99m Sestamibi injected intravenously are shown in Table 10.

Table 10. Radiation Absorbed Doses from Tc99m Sestamibi

	Estimated Radiation Absorbed Dose			
	REST			
	2.0 hour void		4.8 hour void	
Organ	rads/ 30 mCi	mGy/ 1110 MBq	rads/ 30 mCi	mGy/ 1110 MBq
Breasts	0.2	2.0	0.2	1.9
Gallbladder Wall	2.0	20.0	2.0	20.0
Small Intestine	3.0	30.0	3.0	30.0
Upper Large Intestine Wall	5.4	55.5	5.4	55.5
Lower Large Intestine Wall	3.9	40.0	4.2	41.1
Stomach Wall	0.6	6.1	0.6	5.8
Heart Wall	0.5	5.1	0.5	4.9
Kidneys	2.0	20.0	2.0	20.0
Liver	0.6	5.8	0.6	5.7
Lungs	0.3	2.8	0.3	2.7
Bone Surfaces	0.7	6.8	0.7	6.4
Thyroid	0.7	7.0	0.7	6.8
Ovaries	1.5	15.5	1.6	15.5
Testes	0.3	3.4	0.4	3.9
Red Marrow	0.5	5.1	0.5	5.0
Urinary Bladder Wall	2.0	20.0	4.2	41.1
Total Body	0.5	4.8	0.5	4.8
	STRESS			
	2.0 hour void		4.8 hour void	
Organ	rads/ 30 mCi	mGy/ 1110 MBq	rads/ 30 mCi	mGy/ 1110 MBq
Breasts	0.2	2.0	0.2	1.8
Gallbladder Wall	2.8	28.9	2.8	27.8
Small Intestine	2.4	24.4	2.4	24.4
Upper Large Intestine Wall	4.5	44.4	4.5	44.4
Lower Large Intestine Wall	3.3	32.2	3.3	32.2
Stomach Wall	0.2	5.3	0.5	5.2
Heart Wall	0.5	5.6	0.5	5.3
Kidneys	1.7	16.7	1.7	16.7
Liver	0.4	4.2	0.4	4.1
Lungs	0.3	2.6	0.2	2.4
Bone Surfaces	0.6	6.2	0.6	6.0
Thyroid	0.3	2.7	0.2	2.4
Ovaries	1.2	12.2	1.3	13.3
Testes	0.3	3.1	0.3	3.4
Red Marrow	0.5	4.6	0.5	4.4
Urinary Bladder Wall	1.5	15.5	3.0	30.0
Total Body	0.4	4.2	0.4	4.2

Radiopharmaceutical Internal Dose Information Center, July, 1990, Oak Ridge Associated Universities, P.O.Box 117, Oak Ridge, TN 37831, (423) 576-3449.

DRUG HANDLING: The patient dose should be measured by a suitable radioactivity calibration system immediately prior to patient administration. Radiochemical purity should be checked prior to patient administration.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

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

HOW SUPPLIED: DuPont Pharmaceuticals' CARDIOLITE®, Kit for the Preparation of Technetium Tc99m Sestamibi for Injection, is supplied as a 5-mL vial in kits of two (2) (NDC # 11994-001-52); five (5) (NDC # 11994-001-55); and thirty (30) vials (NDC # 11994-001-58), sterile and non-pyrogenic.

Prior to lyophilization the pH is between 5.3 – 5.9. The contents of the vial 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 is one (1) package insert, five (5) vial shield labels and five (5) radiation warning labels. Included in each five (5) vial kit is one (1) package insert, five (5) vial shield labels and five (5) radiation warning labels. Included in each thirty (30) vial kit is one (1) package insert, thirty (30) vial shield labels and thirty (30) radiation warning labels.

This reagent kit is approved for distribution to persons licensed pursuant to the Code of Massachusetts Regulations 105 CMR 120.500 for the uses listed in 105 CMR 120.533 or under equivalent licenses of the U.S. Nuclear Regulatory Commission, Agreement States or Licensing States.

Marketed by: DuPont Pharmaceuticals Company Medical Imaging
331 Treble Cove Road
Billerica, Massachusetts, 01862 USA
For ordering Tel. Toll Free: 800-225-1572
All other business: 800-362-2668
(For Massachusetts and International, call 978-667-9531)

DuPont Pharmaceuticals Company

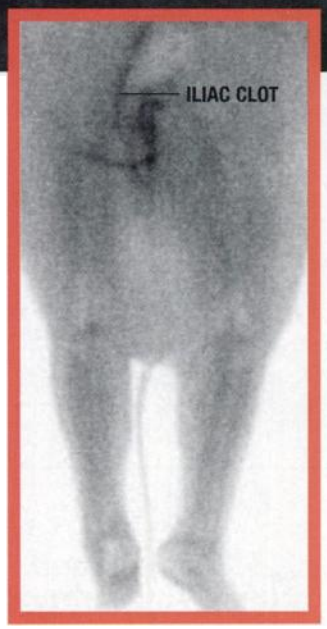
513121-0898 Printed in U.S.A. August 1998

PERFECT HIP REPLACEMENT.

(PE)

But you're still only inches from disaster.

(iliac clot)



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 constraints, AcuTect finds its target — binding preferentially to the glycoprotein (GP) IIb/IIIa receptors found on activated platelets.[1,2] 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.

Please see brief summary of prescribing information on back.

AcuTect®
(Kit for the Preparation of Technetium Tc 99m Apcitide Injection)

The difference is acute.

BERLEX®

WE'VE GOT YOUR SOLUTIONS. Nycomed Amersham

ACUTECT

(Kit for the Preparation of Technetium Tc 99m Apcitide Injection)

BRIEF SUMMARY OF PRESCRIBING INFORMATION

Please consult Full Product Information before using.

DESCRIPTION

AcuTect™, Kit for the Preparation of Technetium Tc 99m Apcitide Injection, is intended for use in the preparation of technetium Tc 99m apcitide, a diagnostic radiopharmaceutical to be used by intravenous injection. Each vial contains a sterile, nonpyrogenic lyophilized mixture which is formulated with 100 µg of bibapcitide, 75 mg of sodium glucoheptonate dihydrate, 89 µg of stannous chloride dihydrate, and sufficient sodium hydroxide or hydrochloric acid to adjust the pH to 7.4 prior to lyophilization. The lyophilized powder is sealed under a nitrogen atmosphere with a rubber closure. The product does not contain an antimicrobial preservative.

Bibapcitide is composed of two apcitide monomers. When sterile, nonpyrogenic Sodium Pertechnetate Tc 99m Injection in 0.9% Sodium Chloride Injection, U.S.P., is added to the vial and heated, the bibapcitide is split and forms a technetium-99m complex of apcitide.

INDICATIONS AND USAGE: AcuTect™ is indicated for scintigraphic imaging of acute venous thrombosis in the lower extremities of patients who have signs and symptoms of acute venous thrombosis.

CONTRAINDICATIONS: None known.

WARNINGS: 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. A fully equipped emergency cart, or equivalent supplies and equipment, and personnel competent in recognizing and treating anaphylactic reactions should be available. (See Adverse Reactions Section.)

PRECAUTIONS

General

The contents of AcuTect™ Kit are intended only for use in the preparation of technetium Tc 99m apcitide, and are not to be administered to the patient without reconstitution.

Hypersensitivity: Small peptides may be immunogenic. Of 642 patients observed for 3 hours after AcuTect™ injection and of whom 169 were monitored for 24 hours, one patient had acute hypotension that began within 10 minutes of injection and, over 60 minutes, progressed to a systolic pressure of 70 mm Hg.

In preliminary studies of IgG binding to apcitide by ELISA assay, IgG binding was not detected. Other measures of immune function (e.g., complement, immune complexes, lymphokines) have not been studied. In preclinical animal models, there was a reduction in the absolute or relative weight of the spleen. The clinical significance of the reduced splenic weight to immune function is not known.

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

Radiopharmaceutical agents 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 governmental agency authorized to license the use of radionuclides.

Urinary excretion of radioactivity occurs over about 24 hours (with 75% occurring during the first 8 hours). Special precautions, such as bladder catheterization, should be taken with incontinent patients to minimize the risk of radioactive contamination of clothing, bed linen, and the patient's environment. Studies have not been done to evaluate the need to adjust the dose of AcuTect™ in patients with renal impairment.

Information for Patients

To minimize the absorbed radiation dose to the bladder, adequate hydration should be encouraged to ensure frequent voiding during the first few hours after AcuTect™ injection. To help protect themselves and others in their environment, patients need to take the following precautions for 12 hours following injection. Whenever possible, a toilet should be used, rather than a urinal, and the toilet should be flushed several times after each use. Spilled urine should be cleaned up completely. Patients should wash their hands thoroughly after each voiding. If blood or urine gets onto clothing, the clothing should be washed separately.

Laboratory Tests

AcuTect™ has been shown to inhibit platelet aggregation. The effect of AcuTect™ on bleeding time in humans has not been studied.

Moderate elevations in liver enzymes were noted in rare cases at three hours and persisted to at least 24 hours following administration of AcuTect™.

Drug Interactions

Clinically detectable drug interactions were not seen or explicitly studied in patients who received technetium Tc 99m apcitide and other concomitant medications. The effect of drugs that increase or decrease prothrombin time on the binding of AcuTect™ to activated platelets has not been studied.

The effect of heparin, warfarin, or aspirin on apcitide binding has not been studied in humans. In animal in vitro and ex vivo models, heparin or aspirin did not change the inhibition of platelet aggregation caused by apcitide. Whether heparin or aspirin change the ability of apcitide to bind to GPIIb/IIIa receptors on activated platelets was not studied. The effect of the duration of anticoagulation on apcitide binding was not studied.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Studies have not been conducted to evaluate carcinogenic potential or effects on fertility. AcuTect™ was not mutagenic in the Ames test or mouse lymphoma test, and it was not clastogenic in the mouse micronucleus test.

Pregnancy

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

Nursing Mothers

Technetium Tc 99m pertechnetate is excreted in human milk. It is not known whether technetium Tc 99m apcitide is excreted in human milk. Caution should be exercised when technetium Tc 99m apcitide is administered to nursing women. Wherever possible, infant formula should be substituted for breast milk until the technetium has been eliminated.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS

Adverse events were evaluated in clinical studies of 642 adults who received technetium Tc 99m 20.0 mCi labeled to approximately 70-100 µg of bibapcitide. Of these adults, 46% were women and 54% men. The mean age was 57.0 years (17 to 95 years). In all patients, adverse events were monitored for at least 3 hours. In a subset of 169 patients, adverse events were monitored for 24 hours. Deaths did not occur during the clinical study period. Following injection of technetium Tc 99m apcitide, a serious episode of hypotension occurred in one patient who had acute hypotension 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 apcitide 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 apcitide.

Table 1: ADVERSE EVENTS REPORTED IN ≥0.5 % OF PATIENTS FOLLOWING AcuTect™ INJECTION IN CLINICAL STUDIES

Number of Patients Exposed to AcuTect™	642
Number of Patients with At Least One Adverse Event	29 (4.5%)
Body As a Whole	21 (3.3%)
Pain (back, leg, chest)	11 (1.7%)
Headache	5 (0.8%)
Cardiovascular System	13 (2.0%)
Hypotension	5 (0.8%)
Hypertension	3 (0.5%)

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

OVERDOSAGE: Clinical consequences of overdosage with technetium Tc 99m apcitide have not been studied.

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

Technetium Tc 99m apcitide should be drawn into the syringe and administered using sterile technique. If nondisposable equipment is used, scrupulous care should be taken 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 apcitide is cleared from the blood by the kidneys. If it is determined that imaging needs to be repeated, additional images may be obtained up to 180 minutes without reinjection. 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 scoring an image as 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 average adult (70 kg) from an intravenous injection of technetium Tc 99m apcitide are listed in Table 2. The values are listed in descending order as rad/mCi and mGy/MBq and assume urinary bladder emptying at 4.8 hours.

Table 2: Radiation Absorbed Doses for a 70kg Adult

Target Organ	rad/mCi	mGy/MBq
Urinary Bladder Wall	0.22	0.060
Kidneys	0.050	0.014
Upper Large Intestine Wall	0.039	0.010
Lower Large Intestine Wall	0.037	0.010
Uterus	0.034	0.0092
Thyroid Gland	0.022	0.0060
Testes/Ovaries	0.020/0.023	0.0053/0.0063
Lungs	0.016	0.0043
Red Marrow	0.0091	0.0025
Breasts	0.0050	0.0013

Dose calculations were performed using the standard MIRD method (MIRD Pamphlet No. 1 rev., Soc. Nucl. Med., 1976). Effective dose equivalent was calculated in accordance with ICRP 53 (Ann. ICRP 18, 1-4, 1988) and gave a value of 0.0093mSv/MBq (0.0034 rem/mCi).

HOW SUPPLIED

Each kit contains one vial containing a sterile, nonpyrogenic, freeze-dried mixture of bibapcitide, stannous chloride dihydrate and sodium glucoheptonate 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 reconstituted injection solution at 20-25° C (68 to 77° F), using appropriate radiation shielding, for up to 6 hours.

The kit should be protected from light.

Rx only

Diatide, Inc.
9 Delta Drive, Londonderry, New Hampshire 03053

Rev. September 1998
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References: 1. AcuTect™ Prescribing Information. **2.** Becker RC. Antiplatelet therapy. *Science & Medicine.* July/August 1996:12-21.

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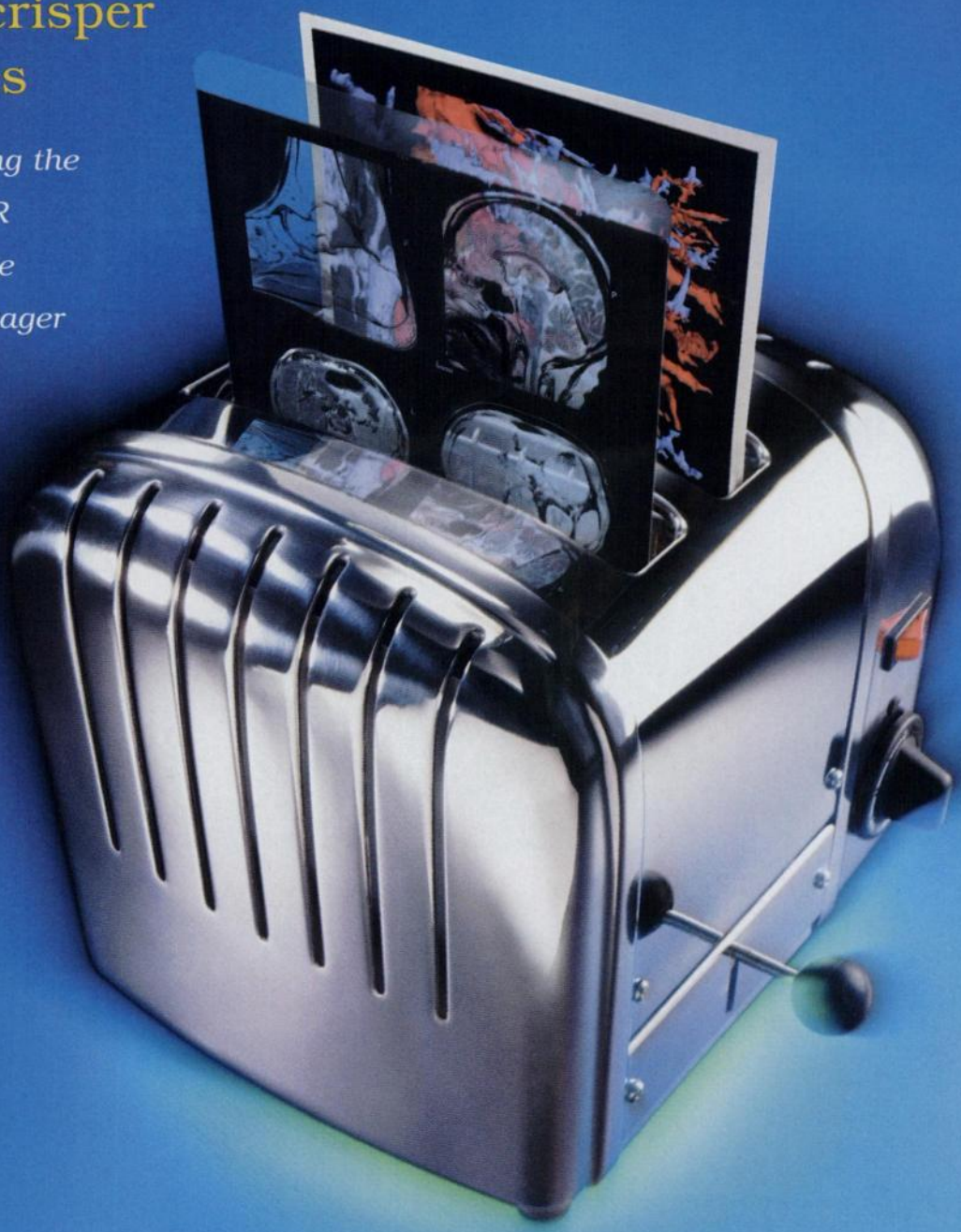

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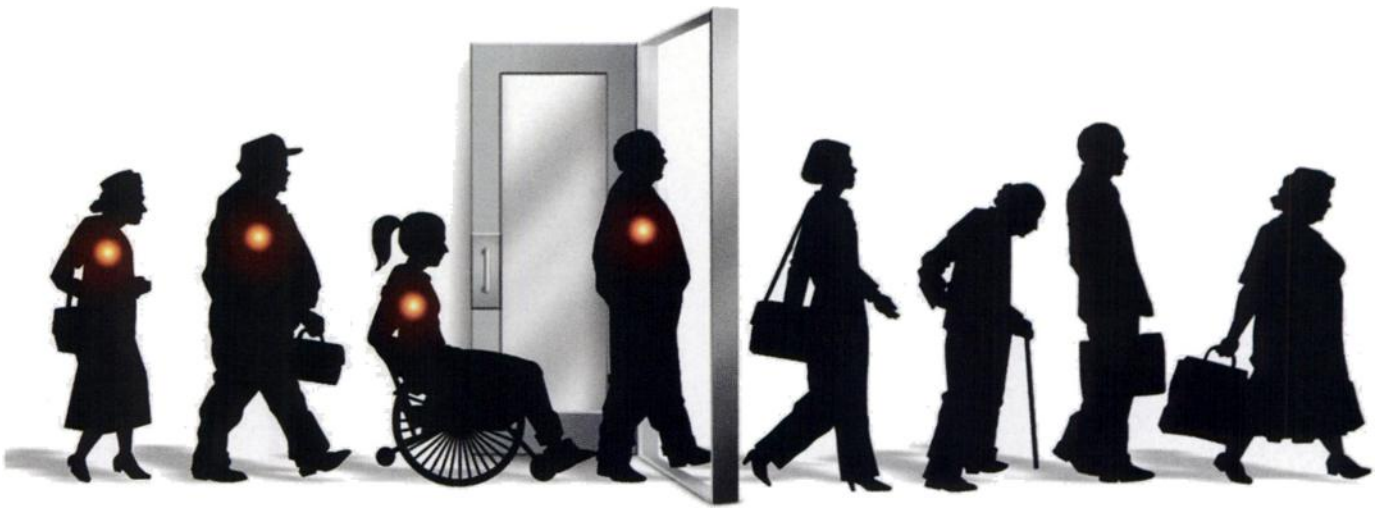

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In studying patients with known or suspected coronary artery disease, care should be taken to ensure continuous cardiac monitoring and the availability of emergency cardiac treatment.

Please see Brief Summary of Prescribing Information on adjacent page.

References: 1. Sridhara BS, Braat S, Rigo P, et al. Comparison of myocardial perfusion imaging with technetium-99m tetrofosmin versus thallium-201 in coronary artery disease. *Am J Cardiol.* 1993;72(14):1015-1019. **2.** Higley B, Smith FW, Smith T, et al. Technetium-99m-1,2-bis[bis(2-ethoxyethyl)phosphino]ethane: human biodistribution, dosimetry and safety of a new myocardial perfusion imaging agent. *J Nucl Med.* 1993;34(1):30-38. **3.** Kelly JD, Forster AM, Higley B, et al. Technetium-99m-tetrofosmin as a new radiopharmaceutical for myocardial perfusion imaging. *J Nucl Med.* 1993;34(2):222-227.

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BS-43-1011A

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Diagnostic Radiopharmaceutical for Intravenous use only

Rx ONLY

Please consult full prescribing information before using. A summary follows:

DESCRIPTION

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

CLINICAL PHARMACOLOGY

General

When technetium Tc99m pertechnetate is added to tetrofosmin in the presence of stannous reductant, a lipophilic, cationic technetium Tc99m complex is formed, Tc99m tetrofosmin. This complex is the active ingredient in the reconstituted drug product, on whose biodistribution and pharmacokinetic properties the indications for use depend.

Clinical Trials

A total of 252 patients with ischemic heart disease or atypical chest pain who had a reason for exercise stress imaging were studied in two open-label, multi-center, clinical trials of Tc99m tetrofosmin (study a and study b). Of these 252 patients there were 212 (83%) males and 40 (17%) females with a mean age of 60.5 years (range 33.7 to 82.4 years). At peak exercise, maximum heart rate achieved and peak systolic blood pressure were comparable after Myoview and thallium-201 exercise studies.

All patients had exercise and rest planar imaging with Myoview and thallium-201; 191 (76%) patients also had SPECT imaging. The Myoview and thallium-201 images were separated by a mean of 5.1 days (1-14 days before or 2-14 days after Myoview). For Myoview imaging, each patient received 185-296 MBq (5-8 mCi) Tc99m tetrofosmin at peak exercise and 555-888 MBq (15-24 mCi) Tc99m tetrofosmin at rest approximately 4 hours later. For thallium-201 imaging, patients received thallium-201 55.5-74 MBq (1.5-2.0 mCi) at peak exercise.

The images were evaluated for the quality of the image (excellent, good or poor) and the diagnosis (with scores of 0 = normal, 1 = ischemia, 2 = infarct, 3 = mixed infarct and ischemia). The primary outcome variable was the percentage of correct diagnoses in comparison to the final clinical diagnosis. All planar images were blindly read; SPECT images were evaluated by the unblinded investigator. A subset of 181/252 (71%) patients had coronary angiography comparisons to the planar images of Myoview or thallium-201.

INDICATIONS AND USAGE

Myoview is indicated for scintigraphic imaging of the myocardium following separate administrations under exercise and resting conditions. It is useful in the delineation of regions of reversible myocardial ischemia in the presence or absence of infarcted myocardium.

CONTRAINDICATIONS

None known.

WARNINGS

In studying patients with known or suspected coronary artery disease, care should be taken to ensure continuous cardiac monitoring and the availability of emergency cardiac treatment.

PRECAUTIONS

General

To minimize radiation dose to the bladder, the patient should be encouraged to void when the examination is completed and as often thereafter as possible. Adequate hydration should be encouraged to permit frequent voiding.

The contents of the Myoview vial are intended only for use in the preparation of technetium Tc99m tetrofosmin injection and are NOT to be administered directly to the patient.

As with all injectable drug products, allergic reactions and anaphylaxis may occur.

Sometimes Tc99m labeled myocardial imaging agents may produce planar and SPECT images with different imaging information.

Technetium Tc99m tetrofosmin injection, like other radioactive drugs, must be handled with care and appropriate safety measures should be used to minimize radiation exposure to clinical personnel. Care should also be taken to minimize radiation exposure to the patient consistent with proper patient management.

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

Drug Interactions: Drug interactions were not noted and were not studied in clinical studies in which Myoview was administered to patients receiving concomitant medication. Drugs such as beta blockers, calcium blockers and nitrates may influence myocardial function and blood flow. The effects of such drugs on imaging results are not known.

Carcinogenesis, Mutagenesis, Impairment of Fertility

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

Tetrofosmin sulphosalicylate was not mutagenic *in vitro* in the Ames test, mouse lymphoma, or human lymphocyte tests, nor was it clastogenic *in vivo* in the mouse micronucleus test.

Pregnancy Category C

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

Nursing Mothers

Technetium Tc99m pertechnetate can be excreted in human milk. Therefore, formula should be substituted for breast milk until the technetium has cleared from the body of the nursing woman.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS

Adverse events were evaluated in clinical trials of 764 adults (511 men and 253 women) with a mean age of 58.7 years (range 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:

Cardiovascular: angina, hypertension, Torsades de Pointes

Gastrointestinal: vomiting, abdominal discomfort

Hypersensitivity: cutaneous allergy, hypotension, dyspnea

Special Senses: metallic taste, burning of the mouth, smelling something

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

DOSAGE AND ADMINISTRATION

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

The first dose of 5-8 mCi (185-296 MBq) is given at peak exercise.

The second dose of 15-24 mCi (555-888 MBq) is given approximately 4 hours later, at rest.

Imaging may begin 15 minutes following administration of the agent.

Dose adjustment has not been established in renally 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/MBq and assume urinary bladder emptying at 3.5 hours.

Estimated Absorbed Radiation Dose (Technetium Tc99m Tetrofosmin Injection)

	Absorbed radiation dose			
	Exercise		Rest	
Target organ	rad/mCi	µGy/MBq	rad/mCi	µGy/MBq
Gall bladder wall	0.123	33.2	0.180	48.6
Upper large intestine	0.075	20.1	0.113	30.4
Bladder wall	0.058	15.6	0.071	19.3
Lower large intestine	0.057	15.3	0.082	22.2
Small intestine	0.045	12.1	0.063	17.0
Kidney	0.039	10.4	0.046	12.5
Salivary glands	0.030	8.04	0.043	11.6
Ovaries	0.029	7.88	0.035	9.55
Uterus	0.027	7.34	0.031	8.36
Bone surface	0.023	6.23	0.021	5.58
Pancreas	0.019	5.00	0.018	4.96
Stomach	0.017	4.60	0.017	4.63
Thyroid	0.016	4.34	0.022	5.83
Adrenals	0.016	4.32	0.015	4.11
Heart wall	0.015	4.14	0.015	3.93
Red marrow	0.015	4.14	0.015	3.97
Spleen	0.015	4.12	0.014	3.82
Muscle	0.013	3.52	0.012	3.32
Testes	0.013	3.41	0.011	3.05
Liver	0.012	3.22	0.015	4.15
Thymus	0.012	3.11	0.009	2.54
Brain	0.010	2.72	0.008	2.15
Lungs	0.008	2.27	0.008	2.08
Skin	0.008	2.22	0.007	1.91
Breasts	0.008	2.22	0.007	1.83

Dose calculations were performed using the standard MIRD method (MIRD Pamphlet No.1 (rev).Society of Nuclear Medicine, 1976). Effective dose equivalents (EDE) were calculated in accordance with ICRP 53 (Ann. ICRP 18 (1-4),1988) and gave values of 8.61×10^{-3} mSV/MBq and 1.12×10^{-2} mSV/MBq after exercise and rest, respectively.

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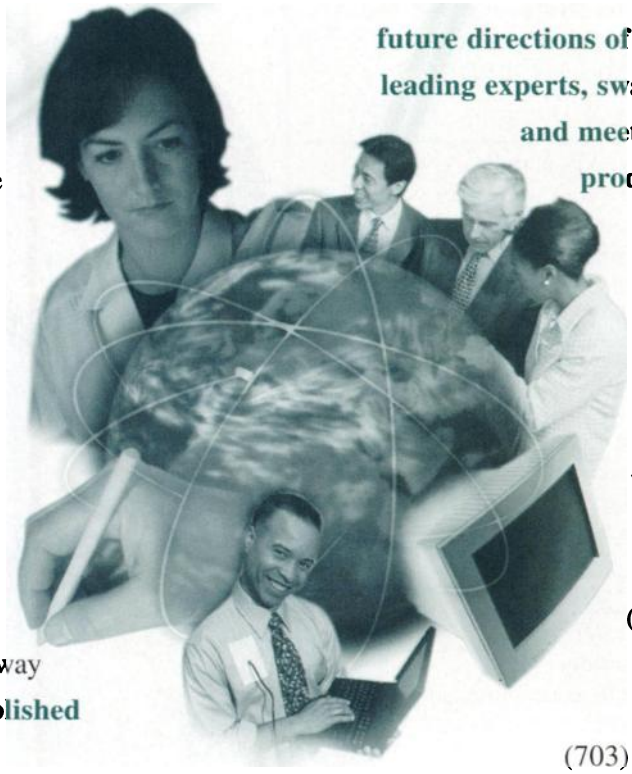

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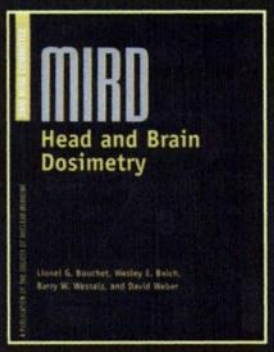

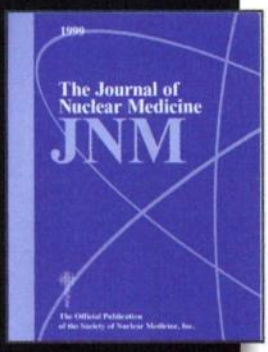

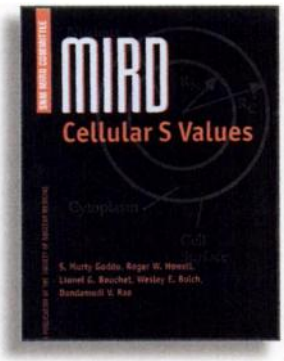

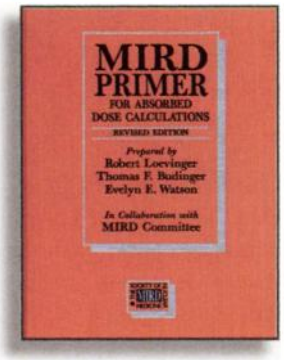

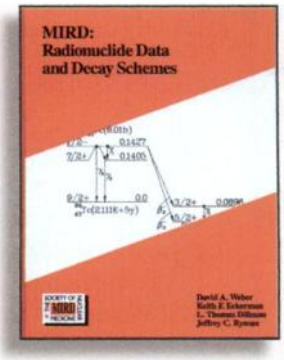

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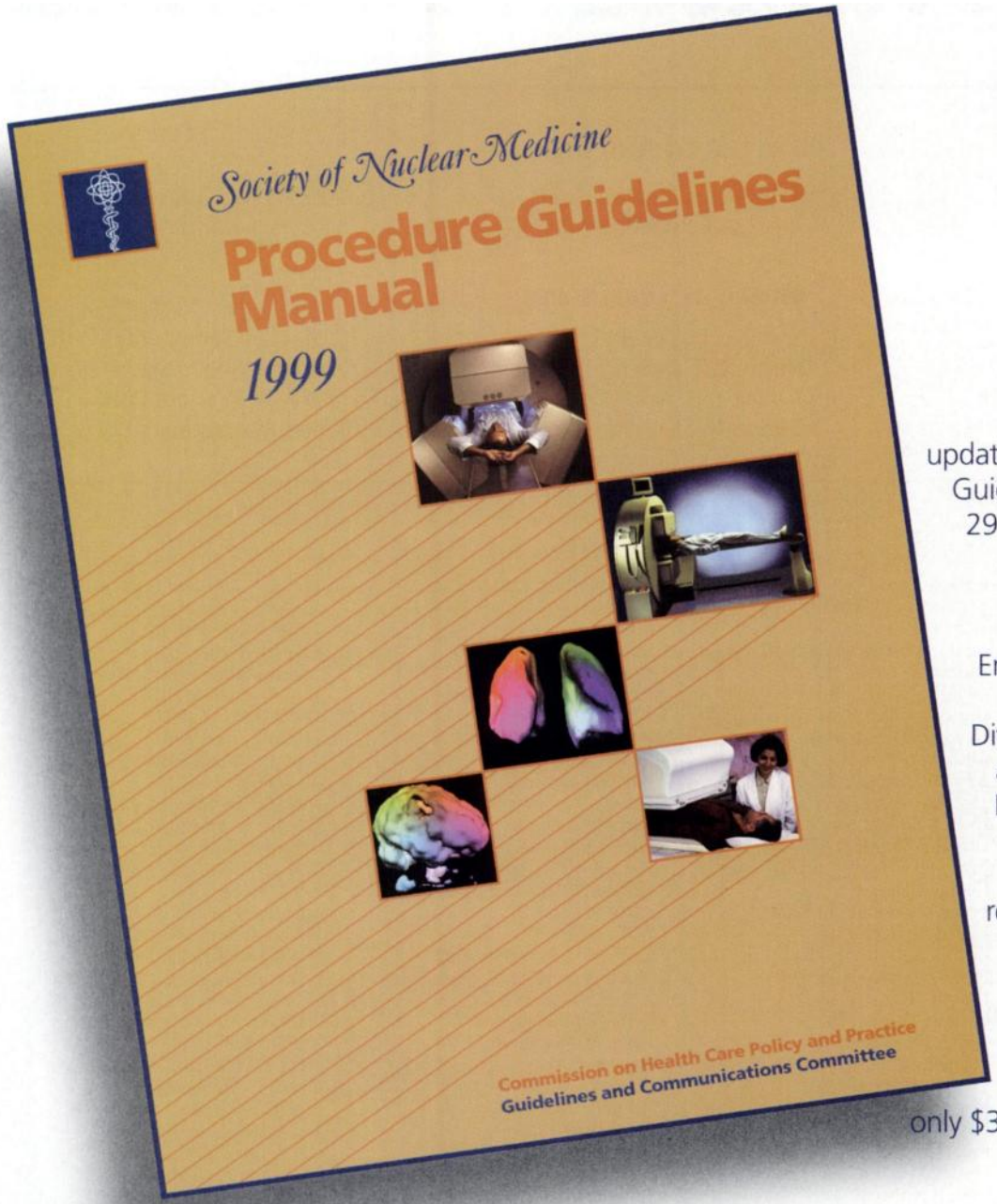

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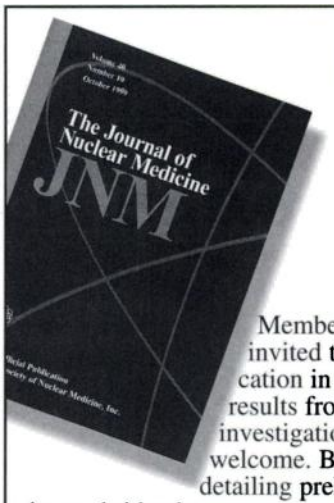

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Information for authors is available at:
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Please forward submissions to:

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Certification Board of Nuclear Cardiology

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Date: October 29, 2000
Time: 7:45 AM to 12:45 PM (Central Time)
Location: Rosemont Convention Center
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Deadline for Receipt of Applications: Early—May 19, 2000
Late—July 21, 2000

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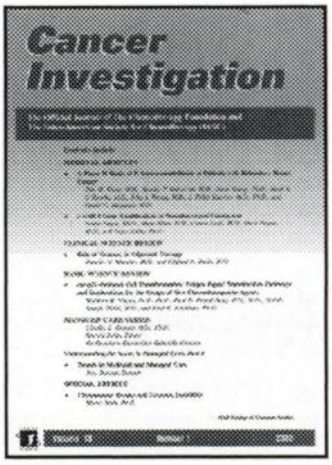

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Positions Wanted

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Positions Needed

Fellowship in Nuclear Medicine
The Nuclear Medicine/Diagnostic Radiology Department at Mayo Clinic has an opening for a one-year fellowship in General Nuclear Medicine beginning July 1, 2000. The department performs approximately 25,000 studies per year utilizing 23 gamma cameras (10 SPECT systems). New cyclotron and PET camera beginning January 2000. Active research areas are cardiology, oncology, gastroenterology and endocrinology. Please send CV to Douglas A. Collins, MD, Mayo Clinic, 200 First Street SW, Rochester, MN 55905. Mayo Clinic is an Equal Opportunity Employer.

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University of North Carolina Radiology Department is seeking a nontenure track clinical Nuclear Medicine Physicist with PhD or MS in physics or related sciences, board certified or eligible in NM, academic rank dependent upon qualifications. Requires experience with radioactive license regulations, quality control of gamma cameras, dose calibrators, NM instrumentation, and PET systems. Familiarity with computer programming and networking associated with NM is desirable. Will Chair Human Use Radiation Safety Committee, share physics teaching duties for Radiology and Nuclear Medicine residents, and be responsible for a 1-1/2 semester physics course for the Nuclear Medicine Technologist training program. UNC is an EOE. Women and minorities are encouraged to identify themselves voluntarily. Please send CV to: William McCartney, MD, Chair, Medical Physicist Search Committee, Radiology, CB 7510, UNC, Chapel Hill, NC 27599-7510.

Nuclear Medicine Resident
The Nuclear Medicine Division at the University of Washington has an opening in July of 2000 for a Nuclear Medicine resident who is interested in a 1–2 year experience in an excellent academic nuclear medicine program. The emphasis will be on clinical nuclear medicine, including significant PET and nuclear cardiology experience. Candidates with at least two years internal medicine training, or board eligibility in another specialty are invited to apply. Interested candidates should send a curriculum vitae with a cover letter requesting an application packet to: Dr. Janet Eary, Director, Division of Nuclear Medicine, University of Washington Medical Center, Box 356113, Seattle, WA 98195-6113.

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Department of Radiology
Ochsner Clinic
1514 Jefferson Highway
New Orleans, LA 70121
Information: (504) 842-3470 or
E-mail: ebluth@ochsner.org

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The Biomedical Imaging Program (BIP) is an extramural program within the Division of Cancer Treatment and Diagnosis of the National Cancer Institute (NCI). This program supports a diverse array of funding mechanisms for the biomedical imaging community related to cancer screening, diagnosis and treatment. Within the BIP, the Molecular Imaging Branch seeks to identify and prioritize opportunities for imaging probe, radio-pharmaceutical, contrast agent, and imaging ligand development in biomedical imaging and the implementation and maintenance of support mechanisms for this research area. The Molecular Imaging Branch seeks and individual with research experience in radiochemistry, contrast agent, or imaging probe development in the area of biomedical imaging.

The incumbent will assist in directing and managing a dynamic extramural research program of national and international scope. The incumbent should have a comprehensive knowledge encompassing some of the following: imaging probe development and validation, radio-chemistry, contrast agent development and validation, or ligand development and validation. More specifically the incumbent should have experience with: (1) imaging probes, ligands, or contrast agents applied to functional, metabolic, or molecular imaging; (2) related validation of these agents both in-vitro and in-vivo; or (3) familiarity with the regulatory issues required for eventual clinical use of such agents. This knowledge is required to effectively identify program priorities and manage the grant portfolios. Experience or familiarity with radio-chemistry is particularly desirable. The incumbent will have the responsibility for providing assistance to the Associate Director of the BIP and designees at the branch level including the Chief of the Molecular Imaging Branch, in the development of new initiatives for both the academic and business sectors, including the small business community. The incumbent will stimulate scientific investigations into biomedical imaging as a collaborative effort with other BIP program staff, especially as they relate to radio-pharmaceutical, contrast agent, imaging probe, and imaging ligand development and validation. In pursuing this goal, the incumbent will also interact closely with other extramural staff at NCI that address the challenge for targeted molecular imaging probe development in cancer.

Candidates should have extensive experience in biomedical imaging probe, ligand, radio-pharmaceutical or contrast agent development and validation. Such experience should include several of the following imaging agent development research areas such as Nuclear Medicine, PET, CT, Magnetic Resonance Imaging and Spectroscopy, Ultrasound, Optical Imaging and Spectroscopy, and/or other imaging technology important for cancer investigations. Applicants with a Ph.D., M.D., or dual degree are sought. Position is open to U.S. citizens only.

Compensation is commensurate with experience and salary history. Benefits-health and life insurance options, retirement, paid holidays, vacation and sick leave. Payment of a recruitment bonus may be offered. Physicians may be eligible for Physicians Comparability Allowance up to $20,000 per year. Payment of travel and transportation expenses will be considered on an individual basis.

Over the next few months the NCI will advertise this position in professional journals with specific information about qualifications, appointment level, and salary. Individuals interested in this position should submit their C.V., bibliography and a statement of interest to:

John M. Hoffman, M.D., Chief: Molecular Imaging Branch
Biomedical Imaging Program, MSC 7440
6130 Executive Boulevard, EPN Room 800
Rockville, Maryland 20892-7440
Tel: 301-496-9531; Fax: 301-480-5785
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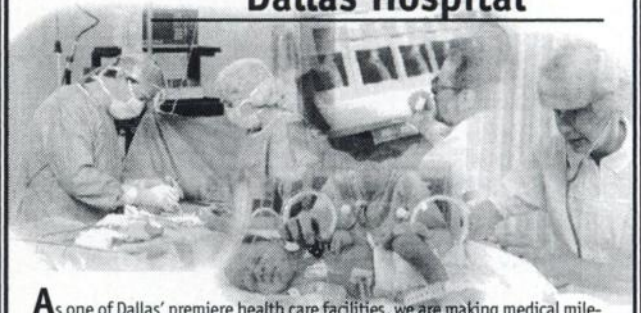

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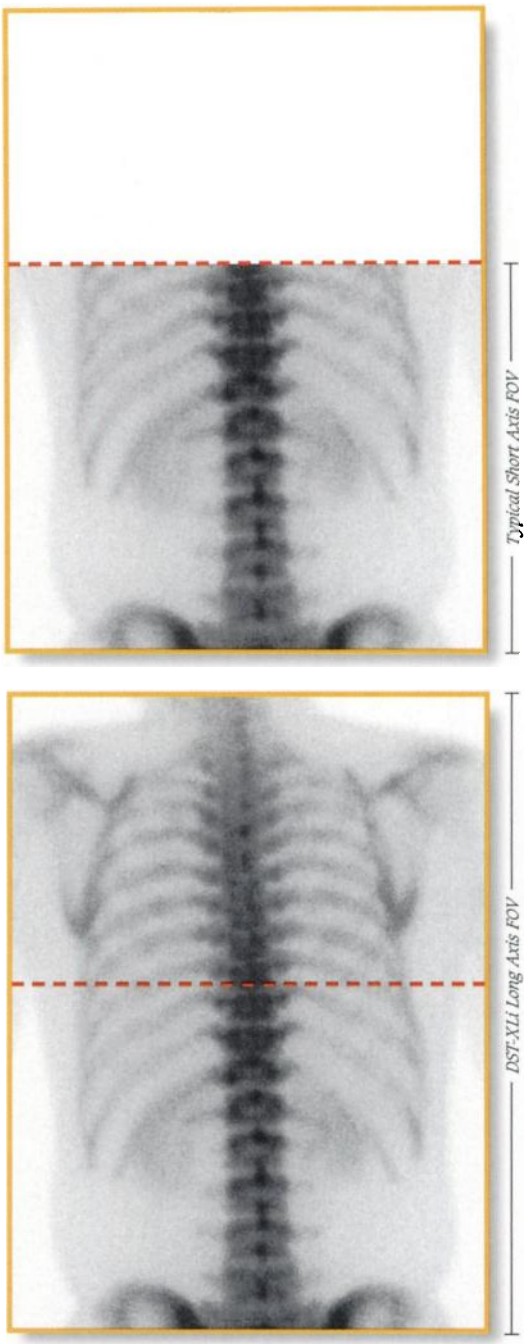

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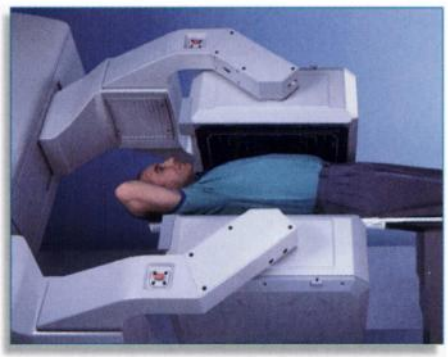

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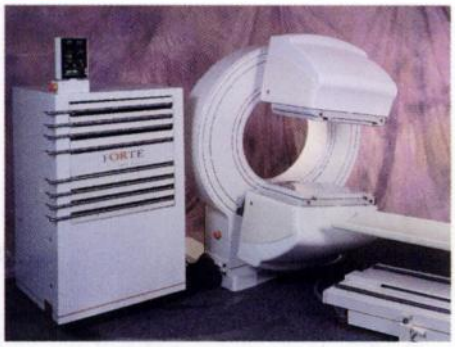

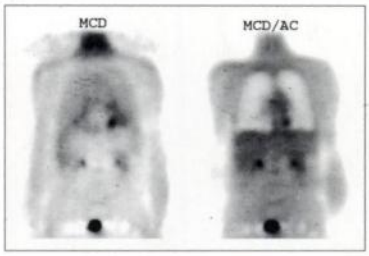

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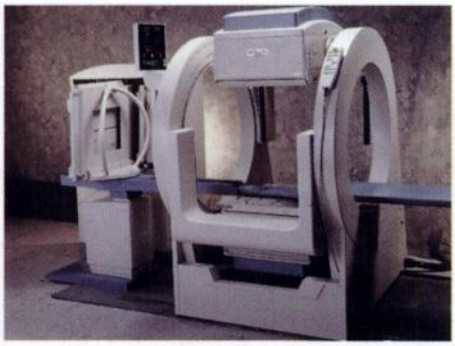

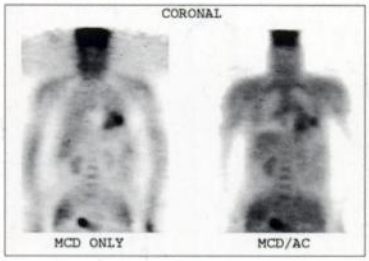

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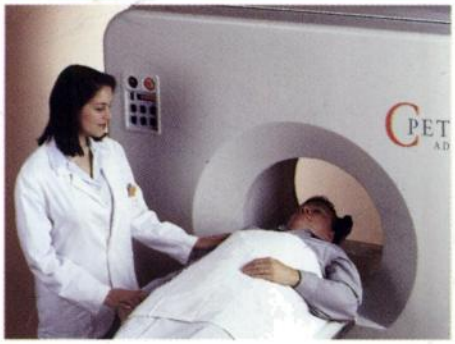

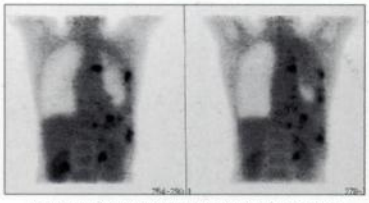

Image courtesy of Centre Hospitalier Universitaire de Liege, Liege, Belgium

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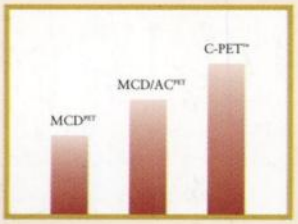

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