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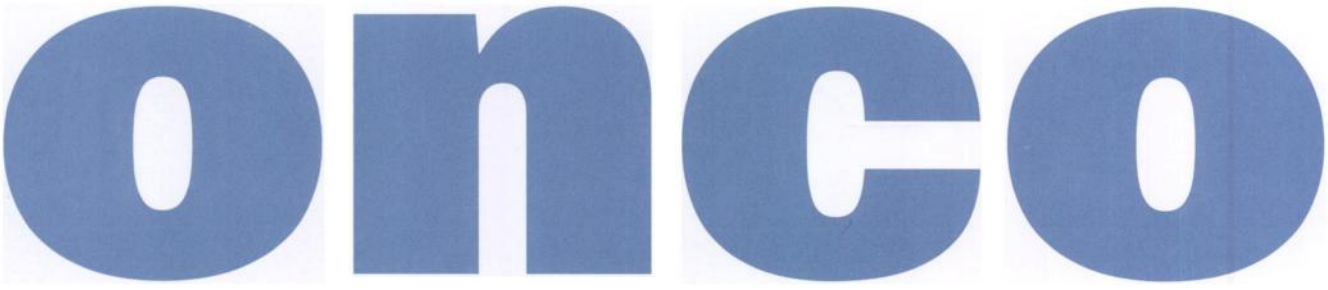

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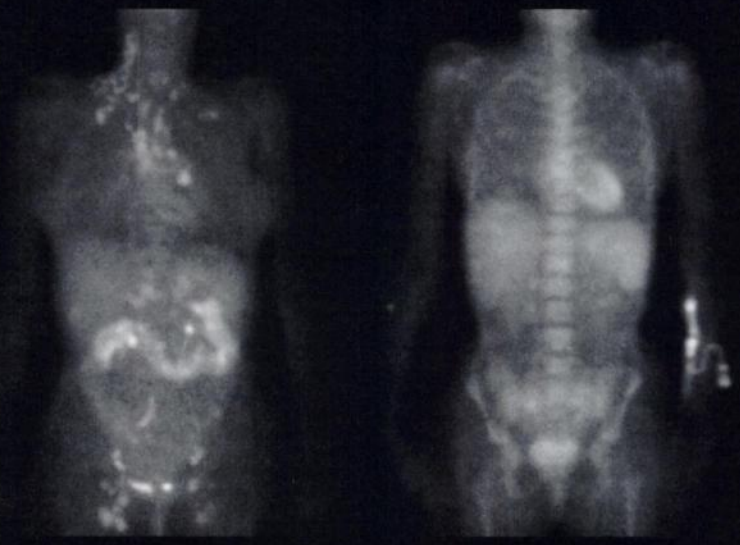

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Give your nuclear department "rapid clearance" capability with MYOVIEW. MYOVIEW clears quickly from the blood, liver, and lungs[1-3] for quality target-to-background ratios and timely imaging (as soon as 15 minutes or up to 4 hours post-injection).[1] The clearance properties of MYOVIEW allow for highly flexible camera scheduling and enhanced patient management. Any way you look at it, you're cleared for efficiency with MYOVIEW.

MYOVIEW is not indicated for use with pharmacologic stress agents.

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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MYOVIEW™

BS-43-1011

Kit for the Preparation of Technetium Tc99m Tetrofosmin for Injection

Diagnostic Radiopharmaceutical for intravenous use only
Code N166A

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-diphosphatetrade-cane], 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.

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

CLINICAL PHARMACOLOGY

General

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

Clinical Trials

A total of 252 patients with ischemic heart disease or atypical chest pain who had a reason for exercise stress 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 Table 1. The values are listed in descending order as rad/mCi and µGy/MBq and assume urinary bladder emptying at 3.5 hours.

Table 1
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	4.98
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.

Manufactured by Amersham International plc
Amersham, United Kingdom

Patent No. 5,045,302 (r)

Distributed by: Medi-Physics, Inc., Amersham Healthcare
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- Somatostatin receptor scintigraphy with OctreoScan detects and localizes primary tumors and metastatic spread often missed by conventional imaging (sensitivity varies 61%-100%, depending on tumor type).[1]
- Whole-body scanning can more definitively confirm the extent of disease.
- You are better able to
  - stage the patient
  - determine diagnostic work-up
  - avoid unnecessary procedures
  - select optimal treatment
  - assess surgical candidates
  - evaluate response to treatment
- Transient adverse effects including dizziness, fever, flush, headache, hypotension, changes in liver enzymes, joint pain, nausea, sweating, and weakness were observed in less than 1% of 538 patients during clinical trials.
- Please see the prescribing information for special considerations regarding patients receiving total parenteral nutrition or concurrent octreotide acetate therapy and patients with insulinoma or impaired renal function.

The accepted standard for GEP tumors*

An emerging choice for small cell lung cancer

**Gastroentero-pancreatic neuroendocrine tumors*

OCTREOSCAN®

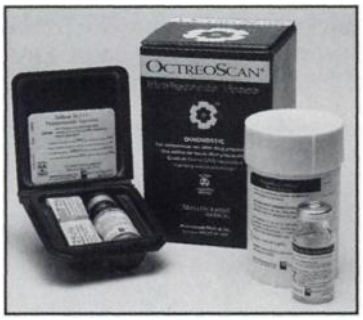
Kit for the Preparation of Indium In-111 Pentetreotide

Please see adjacent page for brief summary of prescribing information.

OCTREOSCAN®

Kit for the Preparation of Indium In-111 Pentetreotide

BRIEF SUMMARY OF PRESCRIBING INFORMATION



DESCRIPTION

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

1) A 10-mL OctreoScan Reaction Vial which contains a lyophilized mixture of 10 µg pentetreotide.

2) A 10-mL vial of Indium In-111 Chloride Sterile Solution.

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

INDICATIONS AND USAGE

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

CONTRAINDICATIONS

None known.

WARNINGS

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

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

PRECAUTIONS

General

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

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

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

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

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

6. Components of the kit are sterile and nonpyrogenic. To maintain sterility, it is essential that directions are followed carefully. Aseptic technique must be used during the preparation and administration of indium In-111 pentetreotide.

7. Octreotide acetate and the natural somatostatin hormone may be associated with cholelithiasis, presumably by altering fat absorption and possibly by decreasing motility of the gallbladder. A single dose of indium In-111 pentetreotide is not expected to cause cholelithiasis.

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

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

Carcinogenesis, Mutagenesis, Impairment of Fertility

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

Pregnancy Category C

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

Nursing Mothers

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

Pediatric Use

Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

The following adverse effects were observed in clinical trials at a frequency of less than 1% of 538 patients: dizziness, fever, flush, headache, hypotension, changes in liver enzymes, joint pain, nausea, sweating, and weakness. These adverse effects were transient. Also in clinical trials, there was one reported case of bradycardia and one case of decreased hematocrit and hemoglobin.

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

DOSAGE AND ADMINISTRATION

Before administration, a patient should be well hydrated. After administration, the patient must be encouraged to drink fluids liberally. Elimination of extra fluid intake will help reduce the radiation dose by flushing out unbound, labelled pentetreotide by glomerular filtration. It is also recommended that a mild laxative (e.g., bisacodyl or lactulose) be given to the patient starting the evening before the radioactive drug is administered, and continuing for 48 hours. Ample fluid uptake is necessary during this period as a support both to renal elimination and the bowel-cleansing process. In a patient with an insulinoma, bowel-cleansing should be undertaken only after consultation with an endocrinologist.

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

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

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

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

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

Radiation Dosimetry

The estimated radiation doses[1] to the average adult (70 kg) from intravenous administration of 111 MBq (3 mCi) and 222 MBq (6 mCi) are presented below. These estimates were calculated by Oak Ridge Associated Universities using the data published by Krenning, et al.[2]

Estimated Absorbed Radiation Doses after Intravenous Administration of Indium In-111 Pentetreotide[3] to a 70 kg patient

	PLANAR		SPECT	
Kidneys	54.16	5.42	108.32	10.83
Liver	12.15	1.22	24.31	2.43
Spleen	73.86	7.39	147.73	14.77
Uterus	6.34	0.63	12.67	1.27
Ovaries	4.89	0.49	9.79	0.98
Testes	2.90	0.29	5.80	0.58
Red Marrow	3.46	0.35	6.91	0.69
Urinary Bladder Wall	30.42	3.04	60.48	6.05
GI Tract				
Stomach Wall	5.67	0.57	11.34	1.13
Small Intestine	4.78	0.48	9.56	0.96
Upper Large Intestine	5.80	0.58	11.59	1.16
Lower Large Intestine	7.73	0.77	15.46	1.55
Adrenals	7.55	0.76	15.11	1.51
Thyroid	7.43	0.74	14.86	1.49
Effective Dose[4] Equivalent	13.03	1.30	26.06	2.61

1. Values listed include a correction for a maximum of 0.1% indium In-114m radiocontaminant at calibration.

2. E.P. Krenning, W.H. Bakker, P.P.M. Kooij, W.A.P. Breeman, H.Y.Oei, M. de Jong, J.C. Reubi, T.J. Visser, C. Bruns, D.J. Kwekkeboom, A.E.M. Reijs, P.M. van Hagen, J.W. Koper, and S.W.J. Lamberts, "Somatostatin Receptor Scintigraphy with Indium-111-DTPA-D-Phe-1-Octreotide in Man: Metabolism, Dosimetry and Comparison with Iodine-123-Tyr-3-Octreotide," The Journal of Nuclear Medicine, Vol. 33, No. 5, May 1992, pp. 652-658.

3. Assumes 4.8 hour voiding interval and International Commission on Radiological Protection (ICRP) 30 model for the gastrointestinal tract calculations.

4. Estimated according to ICRP Publication 53.

HOW SUPPLIED

The OctreoScan kit, NDC 0019-9050-40, is supplied with the following components:

1. A 10-mL OctreoScan Reaction Vial which contains a lyophilized mixture of:
   (i) 10 µg pentetreotide [N-(diethylenetriamine-N,N,N',N"-tetraacetic acid-N"-acetyl)-D-phenylalanyl-L-hemicystyl-L-phenylalanyl-D-tryptophyl-L-lysyl-L-threonyl-L-hemicystyl-L-threoninol cyclic (2→7) disulfide], (also known as octreotide DTPA),
   (ii) 2.0 mg gentisic acid [2,5-dihydroxybenzoic acid],
   (iii) 4.9 mg trisodium citrate, anhydrous,
   (iv) 0.37 mg citric acid, anhydrous, and
   (v) 10.0 mg inositol.

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

2. A 10-mL vial of Indium In-111 Chloride Sterile Solution, which contains 1.1 mL of 111 MBq/mL (3.0 mCi/mL) indium In-111 chloride in 0.02 N HCl at time of calibration. The vial also contains ferric chloride at a concentration of 3.5 µg/mL (ferric ion, 1.2 µg/mL). The vial contents are sterile and nonpyrogenic. No bacteriostatic preservative is present.

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

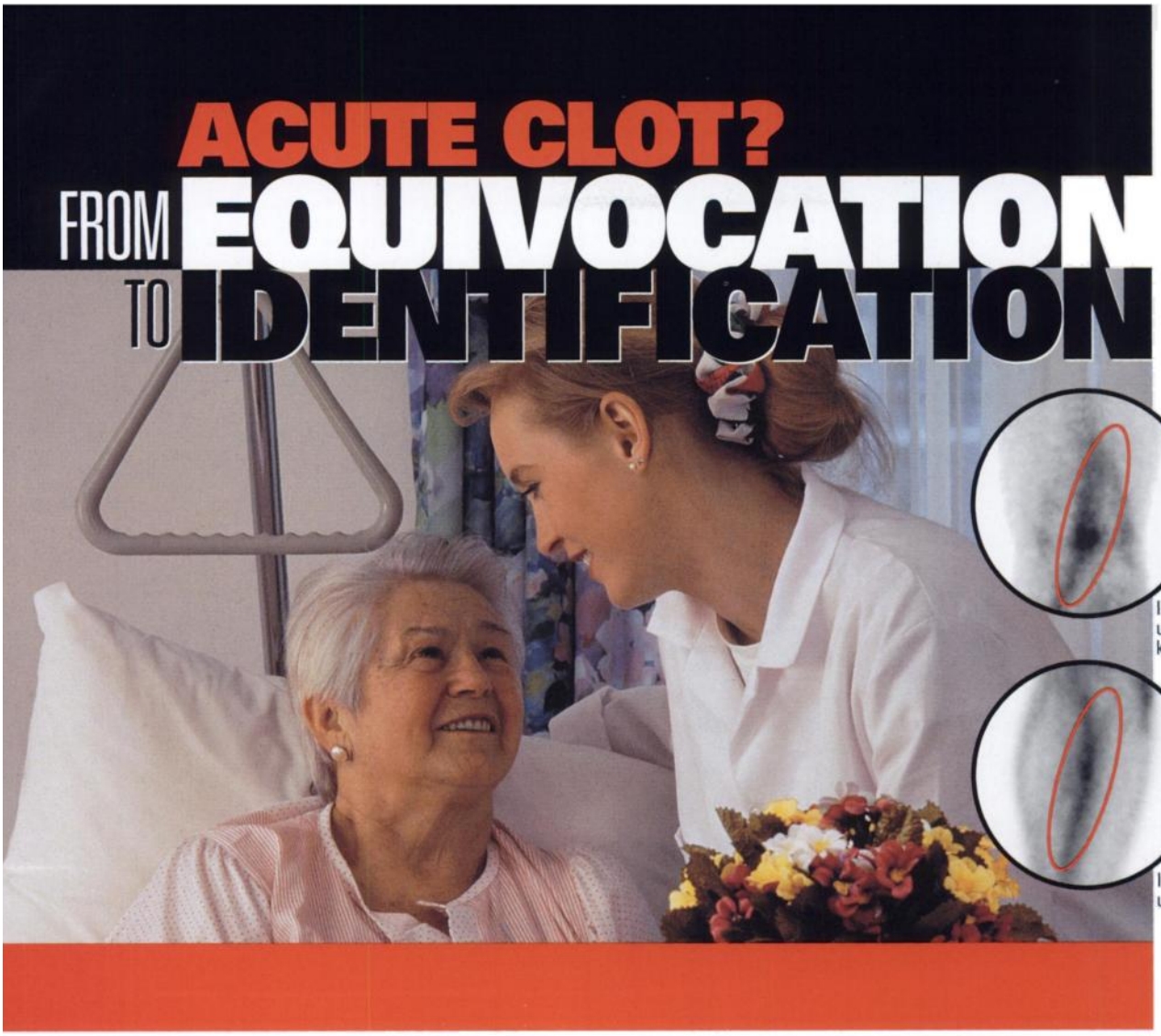
MALLINCKRODT

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

1. Termanini B, Gibril F, Reynolds JC, et al. Value of Somatostatin Receptor Scintigraphy: A Prospective Study in Gastrinoma of its Effect on Clinical Management. *Gastroenterology* 1997;112:335-337.

 MI22701 12/97

ACUTE CLOT?
FROM EQUIVOCATION TO IDENTIFICATION



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

The first imaging modality to target *acute* DVT

AcuTect—a unique, radiolabeled synthetic peptide[1]—is the first to offer you the ability to clearly, safely, and comfortably target *acute* clots. 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.[1] AcuTect binds preferentially to the glycoprotein (GP) IIb/IIIa receptors found on activated platelets.[1,2] AcuTect appears to detect acute and not chronic venous thrombosis. This is based on in vivo and ex vivo animal data; not confirmed clinically.[1] The result is a new sensitivity that challenges venography—the "gold standard."

More than just another diagnostic option—AcuTect is designed for a more confident course of treatment in a potentially life-threatening condition.

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.

For customer service, call 1-877-DIATIDE.

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Please see brief summary of prescribing information on following page.

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
Distributed by: Diatide, Inc. and Nycomed Amersham
60-4500010403

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

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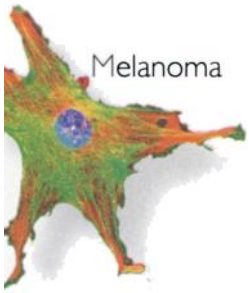

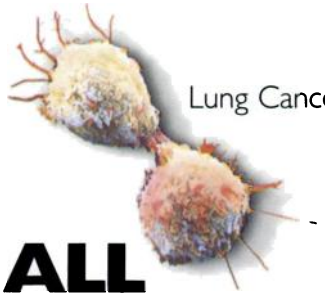

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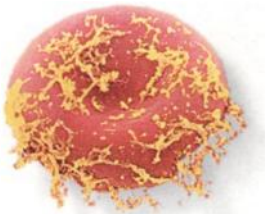

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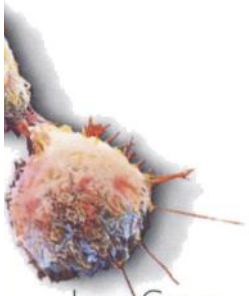
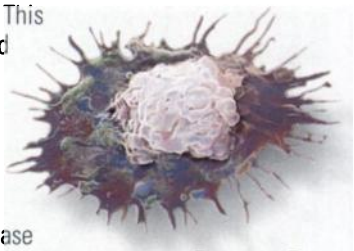
Our unique technology links synthetic *peptides* with the commonly used radioisotope technetium-99m. This inspired combination gives our patented compounds the ability to bind to molecular targets on diseased tissue, for the earliest possible detection of disease.





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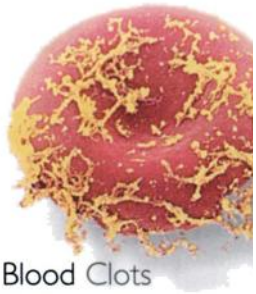

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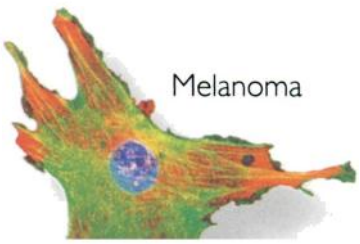

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Positions Available

BC IM/NM

Unique practice opportunity available for expanding two-man group practice for BC IM/NM physician. Practice responsibilities include hospital-based and outpatient NM facilities and private practice of IM with special emphasis on thyroid disease, osteoporosis and diabetes. Qualified applicants send CV to Carolina Nuclear Medicine, 841 Heather Rd., Burlington, NC 27215.

Nuclear Medicine Technologist

Clinishare, a member of Health Midwest has an opening for a Nuclear Medicine Technologist who performs either in vivo or in vitro tasks with limited supervision. Individual must demonstrate competence in performing all procedures with quality to assist physicians in the care of patients. Must be a graduate from an approved school of Nuclear Medicine technology or equivalent and have certification in Nuclear Medicine technology or eligibility for certification. This position requires the technologist to travel to multiple sites and a chauffeur's license is required in some states. Please send resume to: Clinishare, Attn: John Schario, 2316 E. Meyer, 2 North, Kansas City, MO 64132. EOE/Drug Screen Required.

Nuclear Medicine

Progressive subspecialized large private practice radiology group is seeking individual fellowship trained in nuclear medicine. The practice is affiliated with a medical school and residency program, thereby offering the benefits of both private practice and the pursuit of academic interests. Position will include eventual directorship of Nuclear Medicine Department. The practice is located on the Atlantic coastline with a mild climate and all water sports available. Interested persons should send a CV or contact Stephen Carr, MD, Director of Recruiting, Medical Center Radiologists, 6330 North Center Drive, Building 13, Suite 220, Norfolk, VA 23502. Phone: (757) 466-0089. Fax: (757) 466-8017.

Musculoskeletal Radiologist

Progressive subspecialized large private practice radiology group is seeking individual with subspecialty training in musculoskeletal MR. The practice is affiliated with a medical school and residency program, thereby offering the benefits of both private practice and the pursuit of academic interests. The practice is located in coastal Virginia with a mild climate and many recreational activities available with the Chesapeake Bay and Atlantic Ocean nearby. Interested persons should send a CV or contact Stephen Carr, MD, Director of Recruiting, Medical Center Radiologists, 6330 North Center Drive, Building 13, Suite 220, Norfolk, VA 23502. Phone: (757) 466-0089. Fax: (757) 466-8017.

General Radiologist

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Interventional Radiologist

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Nuclear Medicine Radiologist

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NUCLEAR MEDICINE PHYSICIAN (P-4)
Nuclear Medicine Section, Division of Human Health
International Atomic Energy Agency, Vienna, Austria
(Vacancy Notice No. 99/028)

A vacancy has arisen in the Nuclear Medicine Section for a Nuclear Medicine Physician who will be responsible for assisting in formulating, guiding, monitoring and evaluating the Agencyís programme for assisting Member States to apply in vivo radionuclide methods for diagnosis and treatment of diseases and for research in human health. The duties include scientific, administrative, managerial responsibilities and collaborative efforts with other organizations in the creation, review, maintenance and dissemination of systematic overviews in subjects related to nuclear medicine.

Applications are invited from candidates with an advanced postgraduate degree in nuclear medicine with a minimum of 10 years specialised experience in a senior level position in nuclear medicine covering patient care, teaching/training and research. The candidate must have in-depth expertise especially in in-vivo nuclear medicine procedures with sound knowledge of all technical and clinical aspects of such applications, significant research publications of high quality and experience of nuclear medicine conditions in the developing countries. Fluency in English is essential. Knowledge of Spanish and/or French would be an asset.

Initial contract three years (subject to satisfactory performance and evaluation, the appointment may be renewed for a further period of two years), with total annual tax-free emoluments of approximately Austrian Shillings 750 000.- p.a. which include both net base salary and post adjustment, after deduction of the contributions to the United Nations Joint Staff Pension Fund. Additional allowances for dependants. Travel and removal expenses paid. Assignment and repatriation grants. Six weeks annual leave.

Applicants should quote the vacancy notice No. 99/028, their nationality and send the application along with detailed curriculum vitae and a comprehensive list of publications to the Recruitment Unit, Division of Personnel, International Atomic Energy, P.O. Box:100, Wagramerstrasse-5, A-1400 Vienna, Austria. Fax: 43-1-26007) before 30 June, 1999. Further information about this post, and the application procedure, may also be obtained from the IAEA's website at http://www.iaea.or.at//worldatom/vacancies/index.html.

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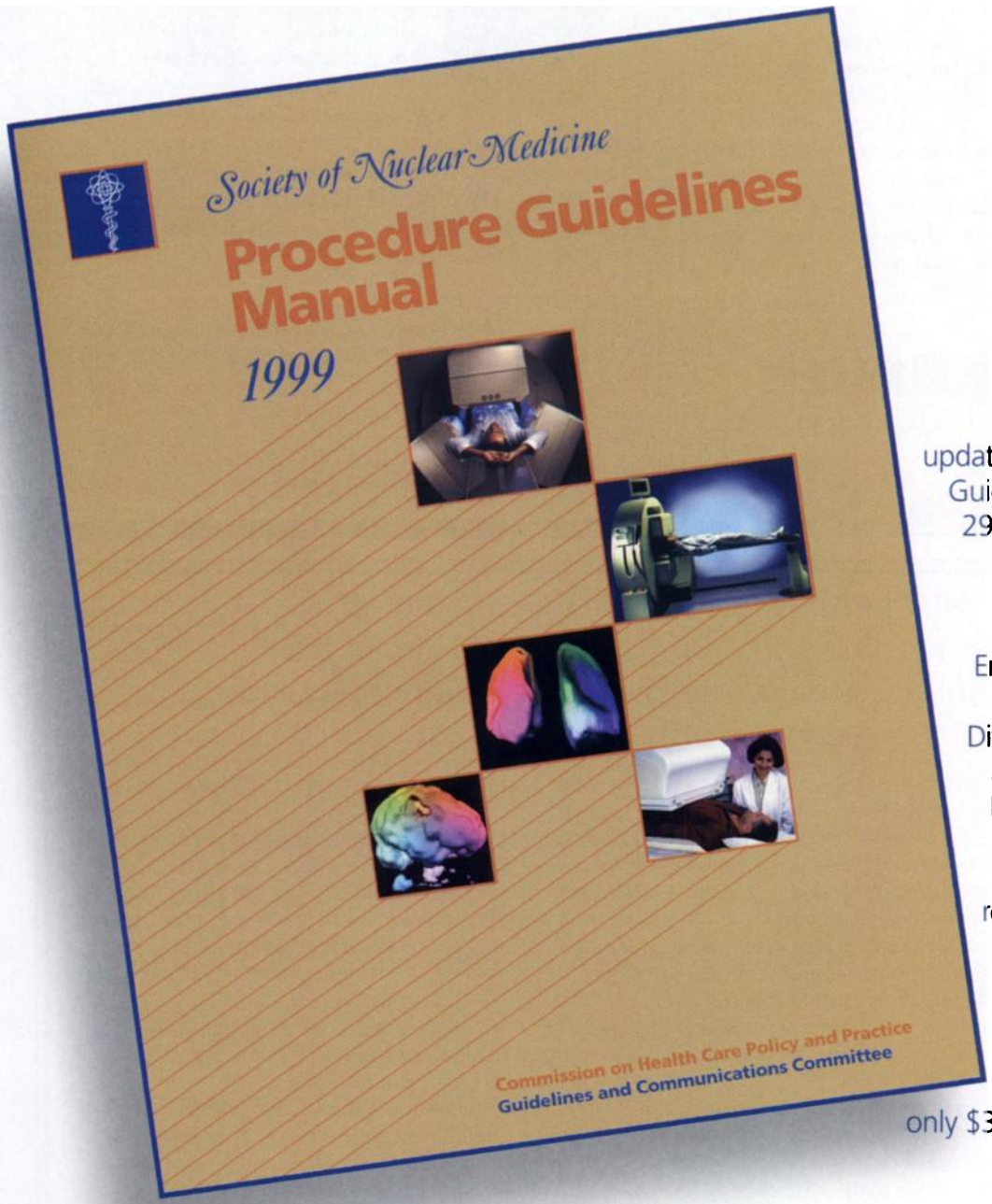

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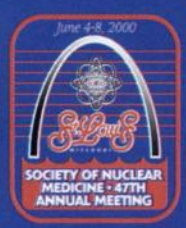

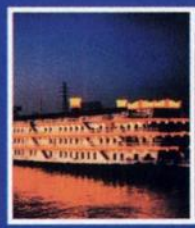

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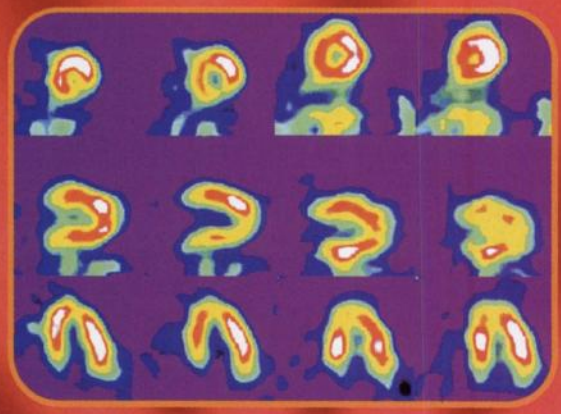

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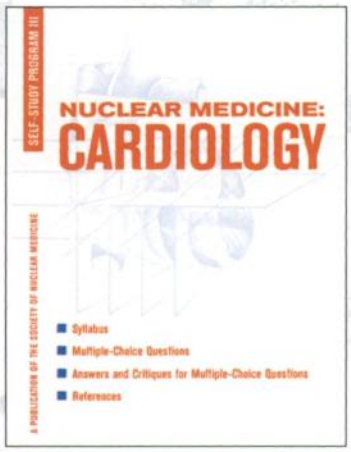

Whether you're a nuclear medicine resident preparing for your board exams, or a veteran clinician, the Nuclear Medicine Self-Study Program series in Cardiology will meet your self-assessment needs. These Self-Study Programs offer an innovative package and approach to ensure that you receive timely, targeted materials as soon as they're available.

The all-new Cardiology Self-Study series offers eight topics, a new topic published every three months. Each topic is clearly written by experts in the field with annotated references, challenging questions and extensive answers with critiques. Publication dates are in parenthesis.

Cardiology Topics
Series Editor: Elias H. Botvinick, MD

Published

Topic 1: Physical and Technical Aspects of Nuclear Cardiology (October 1997)
Contributors: Ernest Garcia, MD, Elias Botvinick, MD, Bruce Hasagawa, PhD and Neil Ratzlaff, MS, CNMT
ISBN 0-932004-52-0
Price: $25 (SNM members); $35 (nonmembers)

Published

Topic 2: Pharmacologic Stress (June 1998)
Contributors: Mario S. Verani, MD, Jeffrey Leppo, MD, Elias H. Botvinick, MD, Michael W. Dae, MD and Susan Alexander, MD
ISBN 0-932004-60-1
Price: $45 (SNM members); $60 (nonmembers)

Published

Topic 3: Cardiac PET Imaging (September 1998)
Contributors: Richard A. Goldstein, MD, Randall A. Hawkins, MD, PhD, Edward M. Geltman, MD, Carl Hoh, MD, Richard Brunken, MD, Yong Choi, PhD, Maria Sciammarella and Elias H. Botvinick, MD
ISBN 0-932004-54-7
Price: $35 (SNM members); $50 (nonmembers)

Published

Topic 4: Radionuclide Assessment of Congential Heart Disease (September 1998)
Contributor: Michael W. Dae, MD

Note: Topics 3 and 4 appear in one volume.

Contributors in remaining Self-Study Cardiology topics include: Drs. Daniel S. Berman, MD, Cedars-Sinai Medical Center, Los Angeles; Elias Botvinick, MD, University of California, San Francisco; Jamshid Maddahi, MD, UCLA, Los Angeles; H. William Strauss, Stanford University Medical Center, Stanford; and Mario S. Verani, Methodist Hospital, Houston.

Topic 5: Myocardial Perfusion Imaging by Single-Photon Radionuclides, part I (February 1998)
ISBN: 0-932004-57-1

Topic 6: Myocardial Perfusion Imaging by Single-Photon Radionuclides, part II (Spring 1999)
ISBN: 0-932004-58-x

Topic 7: Imaging Acute Myocardial Infarction (Summer 1999)
ISBN: 0-932004-55-5

Topic 8: Radionuclide Ventriculography (Fall 1999)
ISBN: 0-932004-56-3

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A similar Self-Study Series on Nuclear Oncology is also available. Look for advertisements in JNM and check SNM's on-line book catalog (www.snm.org) for future updates.

Nuclear Medicine Self-Study Programs in Oncology

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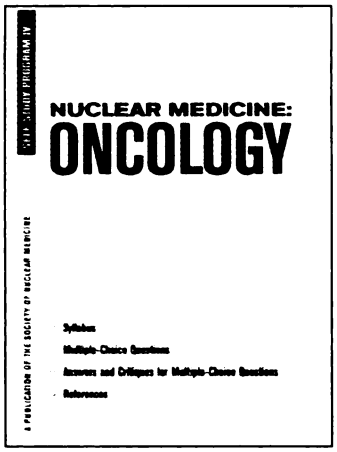

Management of the cancer patient has significantly grown with better diagnostic techniques and chemotherapeutic agents. Learn about these exciting advances in nuclear oncologic imaging with the Self-Study Program series in Oncology. These Self-Study Programs offer an innovative package and approach to ensure that you receive timely, targeted materials as soon as they're available.

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Oncology Topic Booklets
Series Editor: Thomas P. Haynie, MD
Oncology Series Writers: Gerald L. Denardo, MD, Randall Hawkins, MD, PhD, E. Edmund Kim, MD, Alexander J. McEwan, MD, Hani A. Nabi, MD, Patrice K. Rehm, MD, Edward B. Silberstein, MD and Richard Wahl, MD

Published **Topic Booklet 1:** Oncology Overview (July 1997)
ISBN 0-932004-51-2
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Prices for future topics range from $20 to $35.

Topic Booklet 3: Antibody Tumor Imaging (January 1999)
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Topic Booklet 4: PET Tumor Imaging (Spring 1999)
ISBN 0-932004-62-8

Topic Booklet 5: Nonantibody Cancer Therapy (1999)
ISBN: 0-932004-63-6

Topic Booklet 6: Antibody Cancer Therapy (1999)
ISBN: 0-932004-64-4

Topic Booklet 7: Bone Cancer Therapy (1999)
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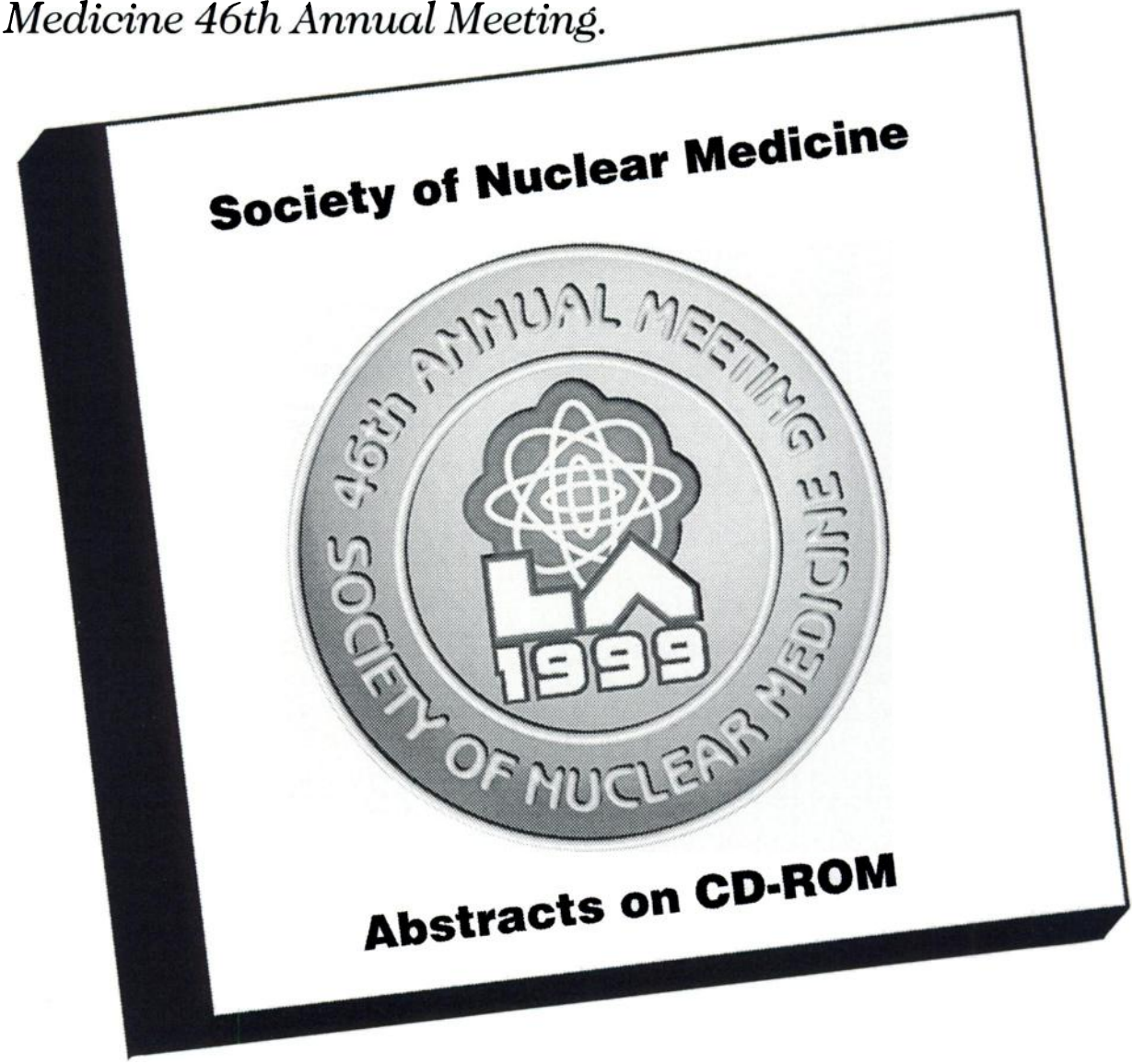
ABSTRACTS ON CD-ROM

For the first time SNM abstracts are available on CD-ROM at the Society of Nuclear Medicine 46th Annual Meeting.



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