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Featuring unique clinical solutions...

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- Emory cardiac quantitative 'toolbox' *
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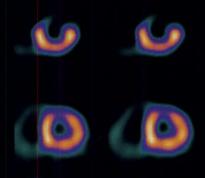
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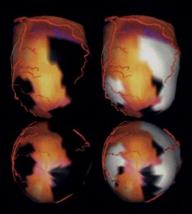
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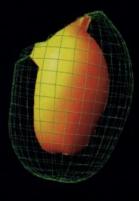
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Inside Information.

Perfusion and function in one test: clinically relevant information.

Cardiolite® provides:

- Both stress perfusion and resting function (wall motion, wall thickening, a quantifiable and reproducible measure of ejection fraction)^{1,2}
- Enhanced diagnostic confidence with a high negative predictive value: A normal stress test correlates with a <1% annualized cardiac event rate³⁻⁵
- Clinically relevant information in a range of situations such as risk assessment, evaluation post-MI, and for chest pain management

Systole

Diastole









LVEF=51%

Gated SPECT images
with CARDIOLITE

For more information, contact DuPont Pharma at 1-800-362-2668 or www.radiopharm.com

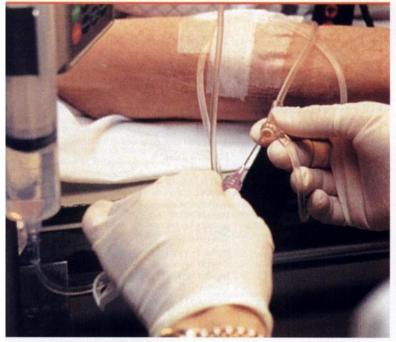
There have been infrequent reports of signs and symptoms consistent with seizure and severe hypersensitivity after administration of Tc99m Sestamibi. Please see brief summary of prescribing information on adjacent page.

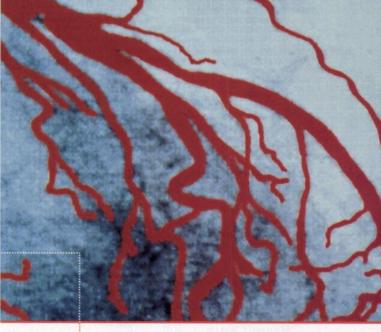


The Confidence You Want-The Information You Need

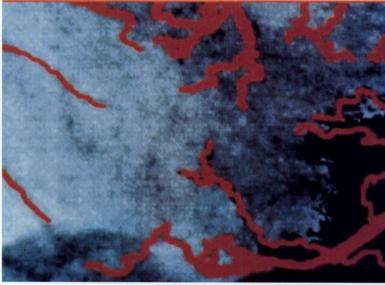


fast START





wide OPEN



Where pharm stress should be

from start to finish

FAST START

- Onset of action is rapid and predictable.
- Maximum coronary hyperemia within 2-3 minutes in most cases.

WIDE OPEN

- Consistently produces maximal vasodilation.
- Blood flow increases 3- to 4-fold over baseline.¹

RAPID RETURN

- <10-second half-life.</p>
- Side effects usually resolve quickly and spontaneously.*

STRONG FINISH

- · Imaging comparable to exercise.
- Lower cost-per-case than dipyridamole.²

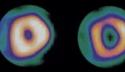
Inside Information.

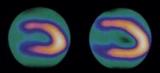
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Systole Diastole





LVEF=51% **Gated SPECT images** with CARDIOLITE

For more information, contact DuPont Pharma at 1-800-362-2668 or www.radiopharm.com

There have been infrequent reports of signs and symptoms consistent with seizure and severe hypersensitivity after administration of Tc99m Sestamibi. Please see brief summary of prescribing information on adjacent page.



The Confidence You Want-The Information You Need

Brief Summary

Kit for the preparation of Technetium Tc99m Sestamibi

F O R DIAGNOSTIC USE

INDICATIONS AND USAGE: CARDIOLITE*, Kit for the preparation of Technetium Tc99m Sestamibi, 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. CAR-DIOLITE* evaluation of myocardial ischemia can be accomplished with rest and cardiovasculor. 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.

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, arrhythmas, 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.

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 prepara-

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:

35%
17%
16%
7%
1%

Carcinogenesis, Mutagenesis, Impairment of Fertility

In comparison with most other diagnostic technetium labeled radiopharmaceuticals, the radiation dose to the ovaries (1.5rads/30mCi at rest, 1.2 rads/30mCi 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]BF₄, 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 (2 20µg/ml), an increase in cells with chromosome aberrations was observed in the in vitro human lymphocyte assay. [Cu(MIBI)₄]BF₄ did not show genotoxic effects in the in vitro mouse micronucleus test at a dose which caused systemic and bone marrow toxicity (9mg/kg, $> 600 \times$ 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: During clinical trials, approximately 8% of patients experienced a transient parosmia and/or taste perversion (metallic or bitter taste) immediately after the injection of Technetium Tc99m Sestamibi. A few cases of transient headache, flushing, edema, injection site inflammation, dyspepsia, nausea, vomiting, pruritus, rash, urticaria, dry mouth, fever, dizziness, fatigue, dyspnea, and hypotension also have been attributed to administration of the agent. Cases of angina, chest pain, and death have occurred (see WARNINGS and PRECAUTIONS). The following adverse reactions have been rarely reported: signs and symptoms consistent with seizure occurring shortly after administration of the agent; transient arthritis in a wrist joint; and severe hypersensitivity, which was characterized by dyspnea, hypotension, bradycardia, asthenia and vomiting within two hours after a second injection of Technetium Tc99m Sestamibi.

DOSAGE AND ADMINISTRATION: The suggested dose range for I.V. administration in a single dose to be employed in the average patient (70kg) is:

370-1110MBq (10-30mCi)

The dose administered should be the lowest required to provide an adequate study consistent with ALARA principles (see also PRECAUTIONS).

When used in the diagnosis of myocardial infarction, imaging should be completed within four hours after administration (see also CLINICAL PHARMACOLOGY).

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.

Ovaries

Total Body

Red Marrow Urinary Bladder Wall

RADIATION DOSIMETRY: The radiation doses to organs and tissues of an average patient (70kg) per 1110MBq (30mCi) of Technetium Tc99m Sestamibi injected intravenously are shown in Table 4.

Table 4. Radiation Absorbed Doses from Tc99m Sestamibi

Estimated Radiation Absorbed Dose 4.8 hour void 2.0 hour void rads/ rads/ mGv/ mGv/ 1110MBq 1110MBq 30mCi 30mCi Organ **Breasts** 0.2 2.0 0.2 1.9 Gallbladder Wall 2.0 20.0 2.0 3.0 5.4 4.2 0.6 20.0 30.0 55.5 Small Intestine 3.0 30.0 Upper Large Intestine Wall 5.4 3.9 0.6 Lower Large Intestine Wall Stomach Wall 40.0 41.1 5.8 4.9 20.0 5.7 2.7 6.4 6.8 15.5 3.9 5.0 6.1 0.5 2.0 0.6 Heart Wall 0.5 2.0 0.6 0.3 0.7 0.7 1.6 0.4 0.5 Kidneys 20.0 Liver 5.8 2.8 Lungs 0.3 0.7 0.7 1.5 0.3 6.8 Bone Surfaces 7.0 15.5 3.4 Thyroid

0.5

	STRESS					
	2.0 ho	our void	4.8 ho	ur void		
Organ	rads/ 30mCi	mGy/ 1110MBq	rads/ 30mCi	mGy/ 1110MBq		
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	0.5	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, (615) 576-3449.

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

Fror to lyophilization the pH is between 5.3-5.9. The contents of the vials are lyophilized and stored under nitrogen. Store at 15-25°C before and after reconstitution. Technetium Tc99m Sestamibi contains no preservatives. Included in each two (2) vial kit are one (1) package insert, six (6) vial shield labels and six (6) radiation warning labels. Included in each five (5) vial kit are one (1) package insert, six (6) vial shield labels and six (6) radiation warning labels. Included in each thirty (30) vial kit are one (1) package insert, thirty (30) vial shield labels and thirty (30) radiation warning labels.

The U.S. Nuclear Regulatory Commission has approved this reagent kit for distribution to persons licensed to use byproduct material pursuant to section 35.11 and section 35.200 of Title 10 CFR Part 35, to persons who hold an equivalent license issued by an Agreement State, and, outside the United States, to persons authorized by the appropriate authority.



Radiopharmaceuticals 4 1

Marketed by **DuPont Radiopharmaceutical Division** The DuPont Merck Pharmaceutical Co. 331 Treble Cove Road

Billerica, Massachusetts, USA 01862 For ordering Tel. Toll Free: 800-225-1572 All other business: 800-362-2668 (For Massachusetts and International, call 508-667-9531)

513121-0296

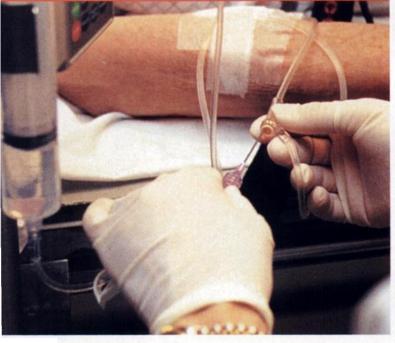
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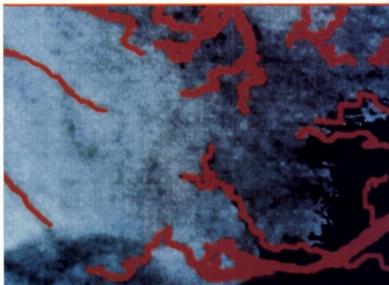
REFERENCES: 1. Nichols K, DePuey EG, Rozanski A. Automation of gated tomographic left ventricular ejection fraction. *J Nucl Cardiol*. 1996;3:475-482. 2. Chua T, Kiat H, Germano G, et al. Gated technetium-99m sestamibi for simultaneous assessment of stress myocardial perfusion, post-exercise regional ventricular function and myocardial viability. *J Am Coll Cardiol*. 1994;23:1107-1114. 3. Stratmann HG, Williams GA, Wittry MD, et al. Exercise technetium-99m sestamibi tomography for cardiac risk stratification of patients with stable chest pain. *Circulation*. 1994;89:615-622. 4. Berman DS, Hachamovitch R, kist H, et al. Incremental value of prognostic testing in patients with known or suspected ischemic heart disease: a basis for optimal utilization of exercise technetium-99m sestamibi myocardial perfusion single-photon emission computed tomography. *J Am Coll Cardiol*. 1995;26:639-647. 5. Hachamovitch R, Berman DS, Kiat H, et al. Exercise myocardial perfusion SPECT in patients without known coronary artery disease. *Circulation*. 1996;93:905-914.



fast START







Where pharm stress should be

from start to finish

FAST START

- Onset of action is rapid and predictable.
- Maximum coronary hyperemia within 2-3 minutes in most cases.

WIDE OPEN

- · Consistently produces maximal vasodilation.
- Blood flow increases 3- to 4-fold over baseline.¹

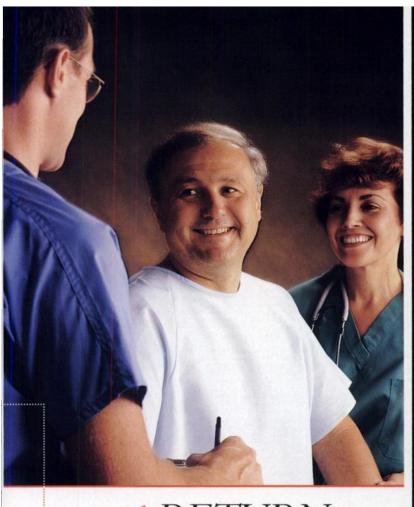
RAPID RETURN

- <10-second half-life.
- Side effects usually resolve quickly and spontaneously.*

STRONG FINISH

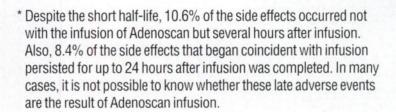
- Imaging comparable to exercise.
- Lower cost-per-case than dipyridamole.2

SNM Annual Meeting Booth #274.

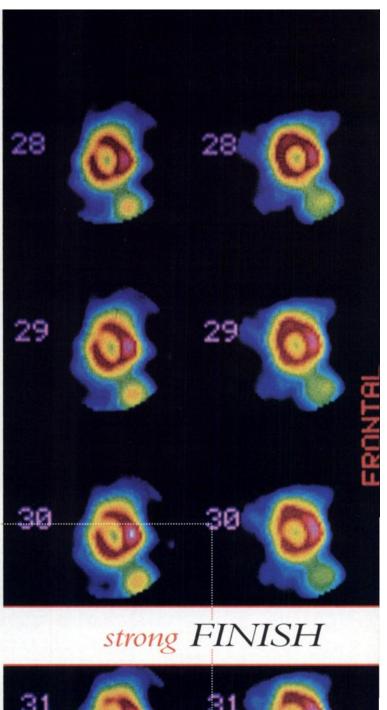


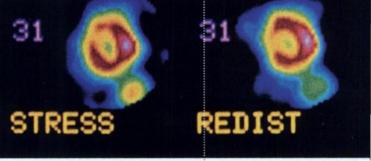
rapid RETURN





Please see the brief summary of prescribing information on the following page.







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- 1. Wilson RF, Wyche K, Christensen BV, et al. Effects of adenosine on human coronary arterial circulation. Circulation. 1990;82:1595-1606.
- Hilleman DE, Lucas BD, Mohiuddin SM, et al. Cost-minimization analysis of intravenous adenosine and dipyridamole in thallous chloride Tl 201 SPECT myocardial perfusion imaging. Ann Pharmacother. 1997;31:974-979.

BRIEF SUMMARY

ADENOSCAN® adenosine

For Intravenous Infusion Only

DESCRIPTION

Adenosine is an endogenous nucleoside occurring in all cells of the body. It is chemically 6-amino-9-beta-D-ribofuranosyl-9-H-purine.

Adenosine is a white crystalline powder. It is soluble in water and practically insoluble in alcohol. Solubility increases by war lowering the pH of the solution.

Each Adenoscan vial contains a sterile, non-pyrogenic solution of adenosine 3 mg/mL and sodium chloride 9 mg/mL in Water for Injection, q.s. The pH of the solution is between 4.5 and 7.5.

INDICATIONS AND USAGE:

Intravenous Adenoscan is indicated as an adjunct to thallium-201 myocardial perfusion scintigraphy in patients unable to exercise adequately. (See WARNINGS).

- Intraversus Adenoscan (adenosine) should not be administered to individuals with:

 1. Second- or third-degree AV block (except in patients with a functioning artificial pacemaker).

 2. Sinus node disease, such as sick sinus syndrome or symptomatic bradycardia (except in patients with a functioning artificial pacemaker).

 3. Known or suspected bronchoconstrictive or bronchoepastic lung disease (e.g., asthma).

 4. Known hypersensitivity to adenosine.

WARNINGS:

Fatal Cardiac Arrest, Life Thre etening Ventricular Arrhythmias, and Myocardial Infarction.

Fatal cardiac arrest, sustained ventricular tachycardia (requiring resuscitation), and nonfatal myocardial infarction have been reported coincident with Adenoscan infusion. Patients with unstable angina may be at greater risk.

Sinoatrial and Atrioventricular Model Block

Convenience and Autoversization in Modern BACK.

Adenoses a (deanosine) exerts a direct depressant effect on the SA and AV nodes and has the potential to cause first-, second- or third-degree AV block, or sinus bradycardia. Approximately 8,3% of patients develop AV block with Adenosean, including first-degree (2,9%), second-degree (2,9%), and third-degree (0,9%) heart block. All episodes of AV block have been asymptomatic, transient, and did not require intervention. Adenosean cause sinus bradycardia. Adenosean should be used with caution in patients with pre-existing first-degree AV block or bundle branch block and should be avoided in patients with high-grade AV block or sinus node dysfunction (except in patients with a functioning artificial pacemaker). Adenosean should be discontinued in any patient who develops persistent or symptomatic high-grade AV block. Sinus pause has been rarely observed with adenosine influsions.

Hypoten:

Adenosan (adenosine) is a potent peripheral vasodilator and can cause significant hypotension. Patients with an intact baroreceptor reflux mechanism are able to maintain blood pressure and tissue perfusion in response to Adenoscan by increasing heart rate and cardiac output. However, Adenoscan should be used with caution in patients with autonomic dystanction, stemotic varbular heart disease, percardial effusions, stemotic cardial artery disease with cerebrovascular insufficiency, or uncorrected hypotensia, due to the risk of hypotensive complications in these patients. Adenoscan should be discontinued in any patient who develops persistent or symptomatic hypotension. Hypertension

Increases in systolic and diastolic pressure have been observed (as great as 140 mm Hg systolic in one case) concomitant with Adenoscan infusion; most increases resolved spontaneously within several minutes, but in some cases, hypertension lasted for several hours.

Adenoscan (adenosine) is a respiratory stimulant (probably through activation of carotid body chemoreceptors) and intravenous administration in man has been shown to increase minute ventilation (Ve) and reduce arterial PCO₂ causing respiratory alkalosis. Approximately 28% of patients experience breathlessness (dyspines) or an urge to breathle deeply with Adenoscan. These respiratory complaints are transient and only rarely require intervention.

intervention. Adenosine administered by inhalation has been reported to cause bronchoconstriction in asthmatic patients, presumably due to mast cell degranulation and histamine release. These effects have not been observed in normal subjects. Adenoscan has been administered to a limited number of patients with asthma and mild to moderate exacerbation of their symptoms has been reported. Respiration compromise has occurred during adenosine infusion in patients with obstructive pulmonary disease. Adenoscan should be used with caution in patients with obstructive lung disease not associated with bronchoconstriction (e.g., emphysems, bronchitis, etc.) and should be avoided in patients bronchoconstriction or bronchospesm (e.g., asthma). Adenoscan should be discontinued in any patient who develops severe respiratory difficulties.

PRECAUTIONS:

Drug Interactions

Drug Interactions
Intravenous Adenoscan (adenosine) has been given with other cardioactive drugs (such as beta adrenergic blocking agents, cardiac glycosides, and calcium channel blockers) without apparent adverse interactions, but its effectiveness with these agents has not been systematically evaluated. Because of the potential for additive or synergistic depressant effects on the SA and AV nodes, however, Adenoscan should be used with caution in the presence of these agents. The vascetive effects of Adenoscan in enhabited by adenosine reception atagonists, such as allybrathrians (e.g., caffeine and theophylline). The safety and efficacy of Adenoscan in the presence of these agents has not been systematically evaluated. The vascective effects of Adenoscan are potentiated by nucleoside transport inhibitors, such as dipyridamole. The safety and efficacy of Adenoscan in the presence of dipyridamole has not been systematically evaluated. Whenever possible, drugs that might inhibit or augment the effects of adenosens should be withheld for at least five half-lives prior to the use of Adenoscan.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Studies in animals have not been performed to evaluate the carcinogenic potential of Adenoscan (adenosine). Adenosine was negative for genotoxic potential in the Salmonella (Ames Test) and Mammalian Microsome Assay.

Adenosine, however, like other nucleosides at millimotar concentrations present for several doubling times of cells in culture, is known to produce a variety of chromosomal attentions. In rats and mice, adenosine administered intrapentonesly once a day for five days at 50, 100, and 150 mg/kg (10-30 (rats) and 5-15 fmice) times human dosage on a mg/M² basis| caused decreased spermatogenesis and increased numbers of abnormal sperm, a reflection of the ability of adenosine to produce chromosomal damage.

Pregnancy Category C

Animal reproduction studies have not been conducted with adenosine; nor have studies been performed in pregnant women. Because it is not known whether Adenoscan can cause fetal harm when administered to pregnant women, Adenoscan should be used during pregnancy only if clearly needed. Pediatric Use

The safety and effectiveness of Adenoscan in patients less than 18 years of age have not been established.

ADVERSE REACTIONS:

The following reactions with an incidence of at least 196 were reported with intravenous Adenoscan among 1421 patients enrolled in controlled and uncontrolled U.S. clinical trials. Despite the short half-life of adenosine, 10,6% of the side effects occurred not with the infusion of Adenoscan but everal hours after the infusion terminated. Also, 8,4% of the side effects that began coincident with the infusion persisted for up to 24 hours after the infusion was complete. In many cases, it is not possible to know whether these late adverse events are the result of Adenoscan infusion.

Flushing	44%	Gastrointestinal discomfort	13%	Second-degree AV block	3%
Chest discomfort	40%	Lightheadedness/dizziness	12%	Paresthesia	2%
Dyspried or urge to breathe deeply	28%	Upper extremity discomfort	4%	Hypotension	2%
Headache	18%	ST segment depression	3%	Nervousness	2%
Throat, neck or jaw discomfort	15%	First-degree AV block	3%	Anhythmias	1%

se experiences of any severity reported in less than 1% of patients include:

Body as a Whole: back discomfort; lower entremity discomfort; weakness.

Cardiovascular System: nonfatal myocardial infarction; life-threatening ventricular arrhythmia; third-degree AV block; bradycardia; palpitation; sinus eatl block; sinus pause; sweating; T-wave changes, hypertension (systolic blood pressure > 200 mm Hg).

Central Nervous System: drowsiness; emotional instability; tremors.

Genital/Urinary System: vaginal pressure; urgency.

Respiratory System: cough.

Special Senses: blurred vision; dry mouth; ear discomfort; metallic taste; nasal congestion; scotomas; tongue discomfort.

OVERDOSAGE:

The half-life of Adenosine is less than 10 seconds and side effects of Adenoscan (when they occur) usually resolve quickly when the infusion is discontinued, although delayed or persistent effects have been observed. Methytkanthines, such as caffeine and theophylline, are competitive adenosine receptor antagonists and theophylline has been used to effectively terminate persistent side effects. In controlled U.S. clinical trials, theophylline (50-125 mg slow intravenous injection) was needed to abort Adenoscan side effects in less than 296 of patients.

DOSAGE AND ADMINISTRATION:

For intravenous infusion only.

Adenoscan should be given as a continuous peripheral intravenous infusion.

The recommended intravenous dose for adults is 140 mog/kg/min infused for six minutes (total tose of 0.84 mg/kg).

The required dose of thallium-201 should be injected at the midpoint of the Adenoscan infusion (i.e., after the first three minutes of Adenoscan).

Thallium-201 is physically compatible with Adenoscan and may be injected directly into the Adenoscan infusion set.

The injection should be as close to the venous access as possible to prevent an inadvertent increase in the dose of Adenoscan (the contents of the Vitbing) being administered. There are no data on the safety or efficacy of alternative Adenoscan infusion protocols.

The safety and efficacy of Adenoscan administered by the intracoronary route have not been established.

Note: Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration.

CAUTION: Federal law prohibits dispensing without prescription.

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PET image of metastatic lung cancer

Moderators: Ruth Tesar and Peter Valk, M.D.



UP-TO-THE MINUTE REPORT... Clinical PET

An ICP/SNM Symposium

Tuesday, June 9th, 1998 5:00 p.m.—8:00 p.m.

The Royal York Hotel 100 Front Street West Toronto, Canada

Course Outline

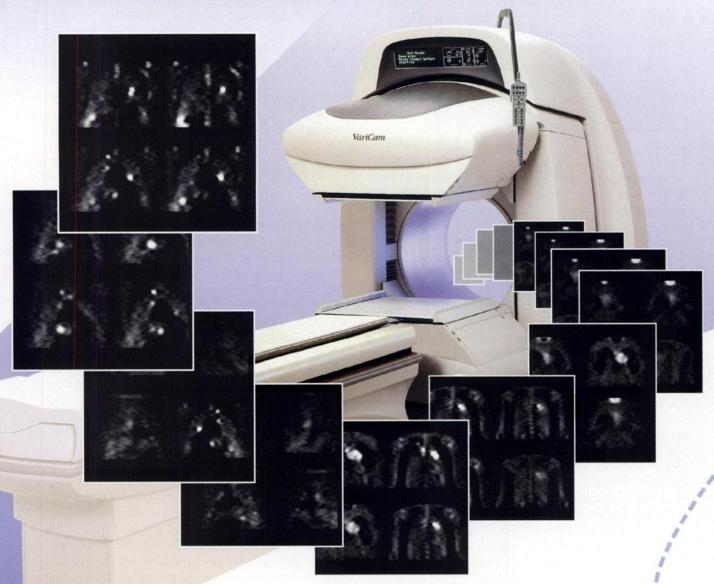
Reimbursement advances have moved PET into the realm of mainstream clinical practice. Much has changed over the last year in the field of PET......come learn about it! In this session, you will develop a full understanding of the current practice of clinical PET. As a "PET intensive" course, attendees will develop an understanding for the types of PET imaging equipment that are available and the options for securing access to PET isotopes. The various approaches to providing PET services will be contrasted, highlighting the relative strengths/weaknesses of each approach. The current clinical applications of PET in oncology will be covered as well as an orientation to the applications that will emerge in the coming years. The session will conclude with an up-to-the-minute report on the current issues facing PET centers, including Medicare Reimbursement and FDA Reform.

Program

5:00 - 5:05 p.m.	Welcome	Ruth Tesar
5:05 - 5:35 p.m.	Setting Up PET Services PET Imaging Equipment PET Isotope Production	R. Edward Coleman, M.D. Brad Holmgren, R.Ph.
5:35 - 6:10	What are the Current "Clinical Applications of PET"? Lung Cancer Colon Cancer and Melanoma	Peter Valk, M.D. George Segall, M.D.
6:10 - 6:25	Break	
6:25 - 7:20	Current Clinical Applications of PET (cont.) Head/Neck and Lymphoma Cost Effectiveness of PET Discussion	Val Lowe, M.D. Peter Valk, M.D.
7:20 - 7:40	Emerging Applications of PET Therapy Monitoring Infection	Richard Wahl, M.D.
7:40 - 8:00	Up-to-the-Minute Report: The Issues Reimbursement FDA Other ICP Activities	Ruth Tesar & Peter Valk

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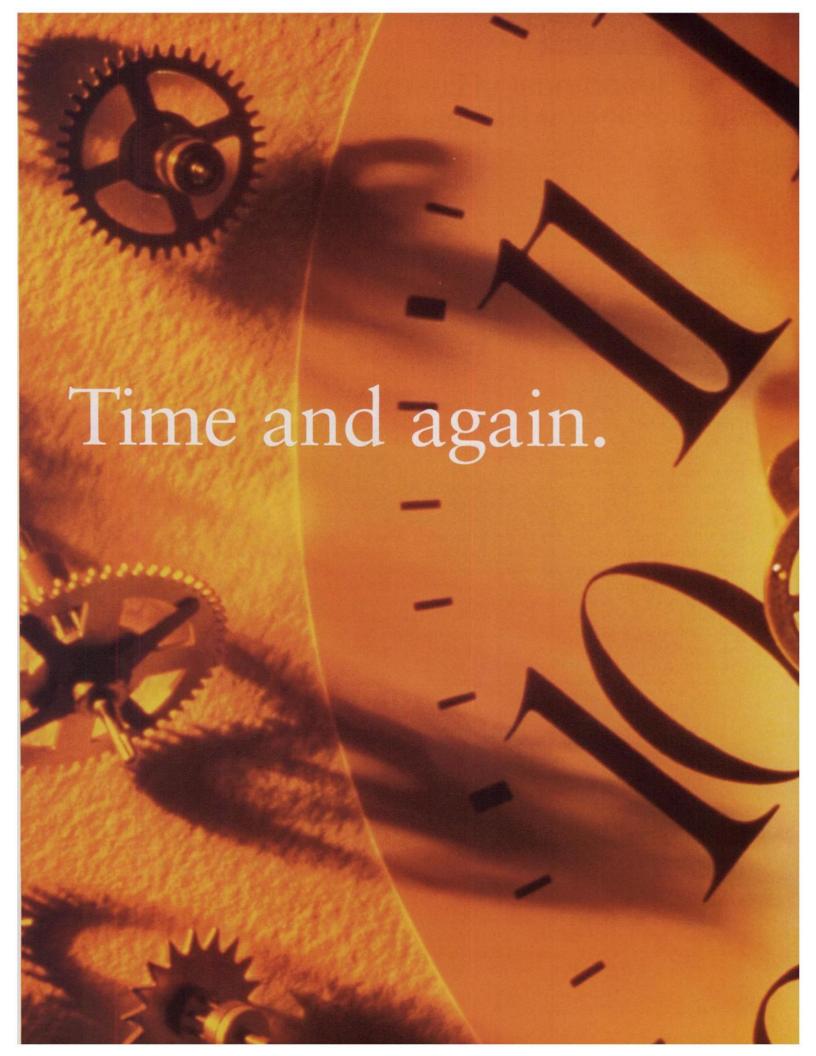
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Please see adjacent page for brief summary of prescribing information.



Kit for the Preparation of Indium In-III Pentetreotide

BRIEF SUMMARY OF PRESCRIBING INFORMATION

DESCRIPTION

OctreoScan* is a kit for the preparation of indium In-111 pentetreotide, a diagnostic ra-pharmacautical. It is a kit consisting of two

- 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

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

WARNINGS

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

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

- Therapy with octreotide acetate can produce severe hypophycemia 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 rectide and are NOT to be administered separately to the patient.
- 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., bisacody) of laculose) before and after administration of indium In-111 pentetreotide (see Dosage and Administration section).
- 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.
- 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
- 7. Octreotide acetate and the natural somatostatin hormone may be associated with cholelithiasis, presumably by altering lat 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 letal 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.

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, 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, abelled pentetreotide by glomerular filtration. It is also recommended that a mild laxative (e.g., bisacody 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 <u>planar</u> imaging is 111 MBq (3.0 mCi) of indium In-111 pentetreotide prepared from an OctreoScan kit. The recommended intravenous dose for <u>SPECT</u> 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

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' to the average adult (70 kg) from intravenous administration of 111 MBq (3 mCl) and 222 MBq (6 mCl) are presented below. These estimates were calculated by Oak Ridge Associated Universities using the data published by Krenning, et al.'

Estimated Absorbed Radiation Doses after Intravenous Administration of Indium In-111 Pentetreotide³ to a 70 kg patient

	PLA	NAR	SF	PECT
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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		i		
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
7.5	* * * * * * * * * * * * * * * * * * * *	*		
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
- Values listed include a correction for a maximum of 0.1% including the 114th reduccontaminant at campitation.
 E.P. Krenning, W.H. Bakker, P.P.M. Kosi, J.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 Rece 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.
- 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

- The Correction with Not 5019-950-90, is supplied with the blowing components:
 A 10-mL OctreoScan Reaction Vial which contains a hyophilized mixture of:

 10 ug pentetreotide [N-(diethylenetriamine-N.N.N.'N-tetraacetic acid-N-acetyl-D-phenylalanyl-L-hemicystyl-L-phenylalanyl-D-tryptophyl-L-hysyl-L-threonyl-L-hemicystyl-L-threoninol cyclic (2-7) disudfide], (also known as octreotide DTPA),
 20 ug gentisic acid (2.5-dihyrdychezoic acid),
 3.4 ug ng gentisic acid, anhydrous,
 3.5 ug gentisic acid, anhydrous, and
 3.5 ug ng inscidium citrate, anhydrous, and
 3.5 ug ng inscidium citrate, anhydrous, and

 - (v) 10.0 mg inositol.

Before hyophilization, 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 (terric ion, 1.2 μg/mL). The vial contents are sterile and nonpyrogenic. No bacteriostatic preservative

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.



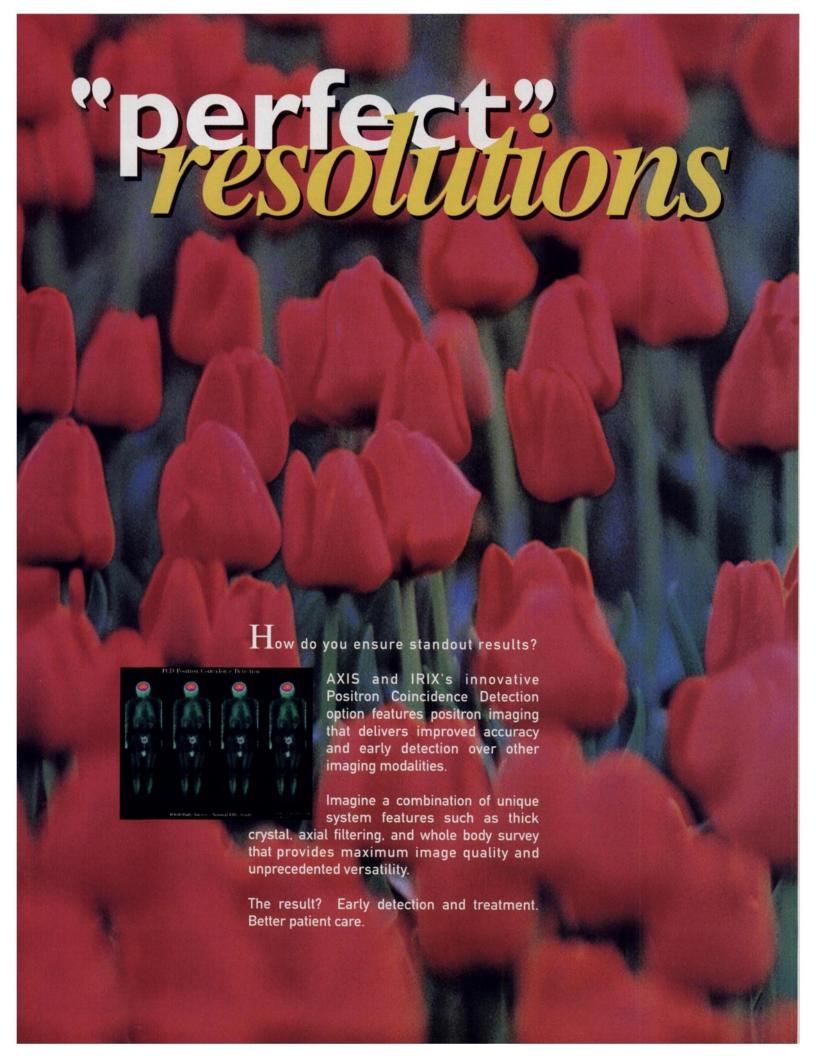
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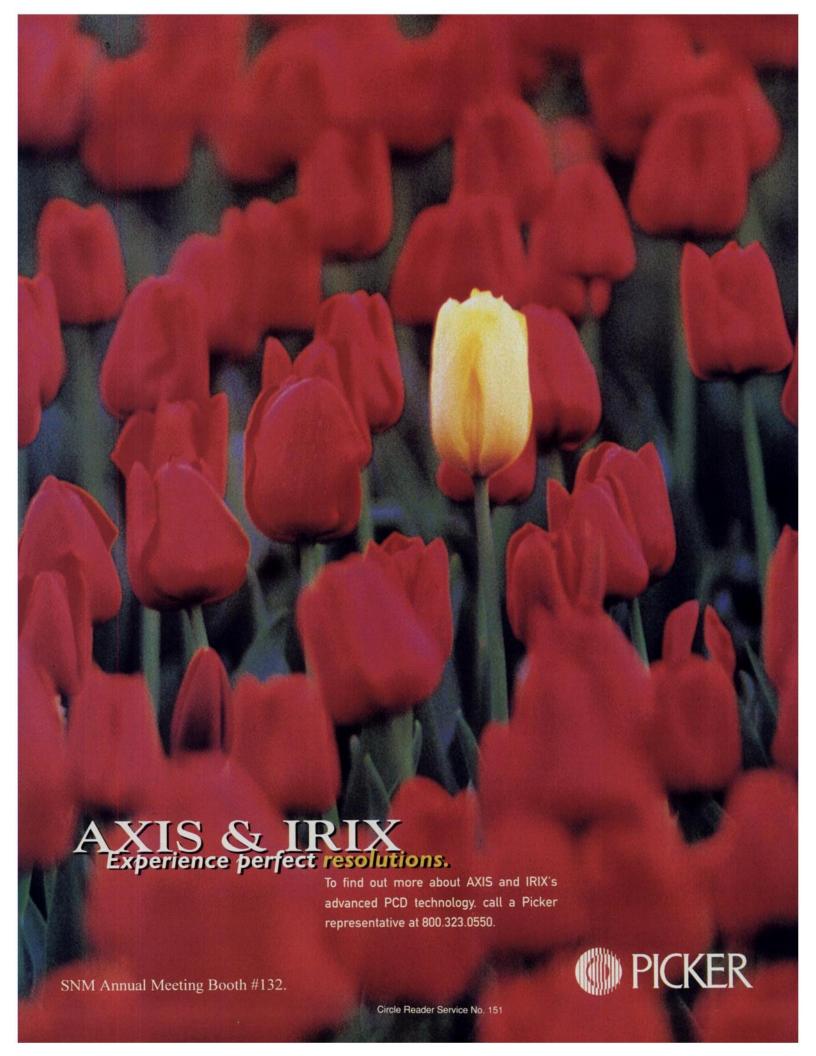
1. Termanini B, Gibril F, Reynolds JC, et al. Value of Somatostatin Receptor Scintigraphy: A Prospective Study in Gastrinoma of its Effect on Clinical Management. Gastroenterology 1997;112:335-337.

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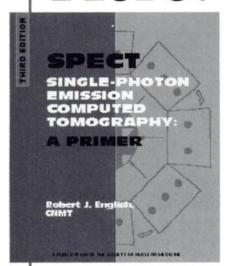
Notice to Authors Submitting Materials to The Journal of Nuclear Medicine

As of July 1, 1998, the address for articles submitted to *JNM* will change. Please mail all manuscripts that may reach the *JNM* office by that date to the following address:

Editor JNM Office Society of Nuclear Medicine 1850 Samuel Morse Drive Reston, VA 20190-5316.

Please also note that the *JNM* "Instructions for Authors" will soon contain significant revisions. Watch for the revised "Instructions for Authors," which will be appearing this summer in the "Publications" section of the SNM web site (www.snm.org) and in the pages of *JNM*.

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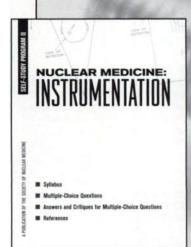
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ne of the goals of the Society of **Nuclear Medicine Technologist** Section (SNM-TS) has been to take an active role in educating the public and the medical community about nuclear medicine procedures and the benefits of this functional imaging modality.



This is the official entry form for the 1998 PR Stars Contest Sponsored by the SNM-TS and Capintec, Inc. Please fill out the entry form and complete the requested information on the reverse side. Based on the information you provide, a panel of judges will evaluate the entries using the point system outlined on the next page and select a winner. All entrants must be a Nuclear Medicine Technologist and a staff member of a hospital or nuclear medicine facility. Entries must be post-marked by December 1, 1998.

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Thanks to the generous support of the 1998 PR Stars corporate sponsor: Capintec, Inc.

1st Place: \$800 for the individual and \$600 for the institution. Up to \$650 in airfare to the 1999 SNM Annual Meeting in Los Angeles to receive your prize! Payment of your pre-registration fee to attend the 1999 SNM Annual Meeting. Your SNM-TS membership dues paid for one year.

2nd Place: \$600 for the individual and \$400 for the institution. Up to \$650 in airfare to the 1999 SNM Annual Meeting in Los Angeles to receive your prize! Payment of your pre-registration fee to attend the 1999 SNM Annual Meeting. Your SNM-TS membership dues paid for one year.

3rd Place: \$350 for the individual and \$250 for the institution. Up to \$650 in airfare to the 1999 SNM Annual Meeting in Los Angeles to receive your prize! Payment of your pre-registration fee to attend the 1999 SNM Annual Meeting. Your SNM-TS membership dues paid for one year.

4th-10th Place: Your SNM-TS membership dues paid for one year.

ENTRY FORM			Mail your entry information (including this completed from) by December 1, 1998 to:
Your Name			Society of Nuclear Medicine
Hospital/Facility			1998 PR Stars Contest 1850 Samuel Morse Drive Reston, VA 20190
Address			Fax: 703-708-9018 Telephone: 703-708-9000
City	State	Zip	
Telephone	Fax		Please complete reverse side

PR-STARS CONTEST

Please describe and document your promotional activities and results. The following point system will be used for judging.

Eligibility:

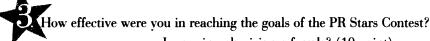
- ★ Nuclear Medicine Technologist
- ★ Staff member of a hospital or nuclear medicine facility
- ★ Entry postmarked by December 1, 1998
- ★ All of the following questions answered in full

Please compose a detailed description, including the goals and objectives, of your nuclear medicine PR activities. 7 points)



Did the goals and objectives you set reflect those of the PR Stars Contest to:

- a. Reinforce nuclear medicine to referring physicians? (10 points)
- b. Promote nuclear medicine to healthcare workers? (5 points)
- c. Increase community awareness? (5 points)
- d. Encourage career paths? (5 points)



- a. Increasing physician referrals? (10 point)
- b. Increasing awareness among healthcare workers? (5 points)
- c. Increasing community awareness? (5 points)
- d. Encouraging career paths? (5 points)
- e. Showing pride in your profession. (5 points)

-	1. What resources did you have available to you and how effectively did you use them? (budget, manpower, media, etc) (13 points)
4	Can your program be used easily by others? Please explain(5 points)
4	Was your program cost effective? Please explain (5 points)
4	When did your nuclear medicine PR activity take place? (no points)

Please provide a detailed time-line of th	planning and implementation of	your program. (10 points)
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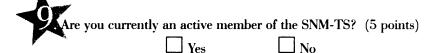
For example:

March 10

Strategic planning session with staff technologists

May 1

Drafted nuclear medicine article for facility newsletter

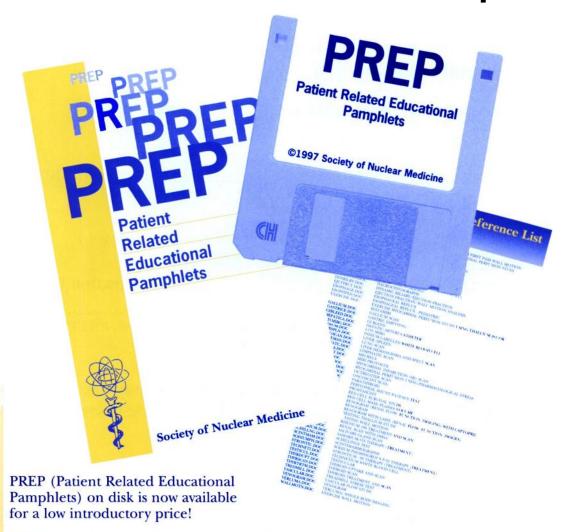


Thank you for your entry! Good Luck!

Val Cronin, CNMT 1997 - 1998 Nuclear Medicine Week Chairperson Susan Gavel, CNMT 1998 - 1999 Nuclear Medicine Week Chairperson

Introducing PREP

Patient Related Educational Pamphlets



PREP provides patient information on diagnostic and therapeutic nuclear medicine procedures on a diskette in Microsoft WORD that you can reformat and customize to meet the needs of your institution. The PREP package includes: (1) a diskette of procedures (2) a printed reference page with all file names and (3) samples of how the PREP information can be used.

PREP will enable you to easily provide important information to your patients — promoting confidence and an understanding of their nuclear medicine procedure. Help to establish nuclear medicine as an integral part of patient care by giving referring physicians the PREP information.

PREP meets JCAHO standards for patient education and helps you adhere to accreditation compliance requirements.

The cost is only \$55 for SNM Members and \$65 for non-members.

To order, please use the form on the following page.



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\$65 for non-members plus \$3 shipping/handling.
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Payment Information: (Pre-payment required. No purchase orders accepted.) Charge myVISA orMASTERCARD
Card Number: Expiration Date:
Signature:
Mail of fax this form and completed credit card information to: SNM, PREP, 1850 Samuel Morse Drive, Reston, VA 20190. Fax: 703-708-9018
My check made out in the full amount and made payable to SNM is enclosed. (Mail form and check to: SNM, PREP, 1850 Samuel Morse Drive, Reston, VA 20190.)
Shipping Information: (No P.O. boxes) Yes, I have read and will comply with the copyright, duplication and disclaimer information listed below.
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The Society of Nuclear Medicine (SNM) has made every effort to insure that the information contained on the PREP diskette is complete and accurate. However, since some testing techniques vary, each user should take steps to assure that the information is applicable to its tests. Nothing contained on the PREP diskette should be construed as either a standard of care of SNM or as a recommendation for patient care by SNM. SNM disclaims any responsibility or liability of whatsoever nature or kind for any use made of the materials provided herein. User should advise patients that this information is provided for information purposes only and is not intended as a substitute for discussion between patient and physician.

License agreement terms and conditions will appear on the shipping package.



CELEBRATE NUCLEAR MEDICINE WEEK! OCTOBER 4 - 10, 1998

T-shirt: White 100% cotton t-shirt with the Nuclear Medicine Week logo featured on the front.

Sizes: L and XL (quantities limited)

Poster: Display the poster prominently in your medical facility, use it as a teaching tool or give it to referring physicians to promote nuclear medicine.

Buttons & Stickers: Get the nuclear medicine message out by wearing the buttons or using the stickers on all your correspondence. A perfect and inexpensive give-away.

Patient Pamphlets: Use the SNM Patient Pamphlets to educate your patients, the public and referring physicians about nuclear medicine. Use this form to order the *Benefits of Nuclear Medicine* or call Matthews Medical Books at 1-800-633-2665 to request this or other pamphlets in the series. (Liver, Bone, Renal, Brian, Ovarian & Colorectal, Breast, Prostate, Cardiac Stress-Rest Test and Radioiodine)

ORDERING INFORMATION: Pre-payment via check, VISA or Mastercard required for all orders.

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CHECK & CREDIT CARD ORDERS
Society of Nuclear Medicine
c/o MidPoint National
P.O. Box 411037

Kansas City, MO 64141-1037

Faxed orders are accepted if submitted using this form and includes the completed credit card information required below.

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T-shirt (size: XL)		\$10.00 each	
Poster		\$5.00 each	
Stickers		\$.25 each	
Buttons		\$1.00 each	
SNM Patient Pamphlet: nefits of Nuclear Medicine		\$20.00 for pack of 50	
Guidelines for Promoting Nuclear Medicine		FREE	FREE
MERCHANDISE TOTAL			\$
Tax: In VA - 4.5%. In KS - 6	6.9%		\$
Shipping: (allow 2 -4 week If your merchandise total is:		\$10.01-\$20.00 add: \$5.00 00 \$30.00 or more add: \$10.00	\$
Express Delivery and F Express charge in addition to t Express: allow 3-5 days for de	he regular shipping rates.		\$
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#NMIO3



#NM202

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Available in White, Cardinal Red & Royal Blue Sizes: M, L, XL, 2X*



#NMIO4

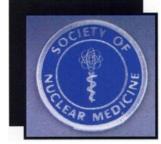
Grace your desk with this 3" diameter ebony marble paperweight with silver SNM medallion plate. A keepsake you'll treasure for years to come.



#NMIOO

This distinguished 13 oz. presidential collection clear glass mug is tastefully accented with a gold rim and SNM embossed gold logo.

Microwavable!!!!



#NMIOI

This handsome blue and white embroidered SNM patch is the perfect accompaniment to any garment. Celebrate your profession by purchasing one for each member of your staff.



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Show your SNM team spirit by wearing this natural cotton twill cap. One size fits all, your choice of visor colors:
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#NM200

Like your favorite sweater, this heavyweight taslan nylon jacket with trail fleece lining and embroidered SNM logo will be irreplaceable.

Available in Royal Blue, Navy or Black Sizes: S, M, L, XL, 2X*, 3X*

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	NM200	Jacket -(<i>Please add \$3.00 for 2X, \$5.00 for 3X</i>)			\$60.00*	
	NM202	Golf Shirt-(Please add \$3.00 for 2X)			\$18.00*	
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Candidates will be responsible for working with the sales force in demonstrating products and training customers. Qualified candidate will have a minimum of 5 years experience in NM. Must be registered in ARRT or CNMT. Candidates must be open to extensive traveling (90%) and may need to relocate.

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ABNM (dual boards desirable) entry level position for outpatient imaging center in Boca Raton, Florida. Instrumentation includes Siemens 951R PET, Pegasys/GE nuclear, Lunar DPX-L Bone Density. Ongoing clinical research revolves around applications using monoclonal antibodies. Send resume to: P.O. Box 11697, Ft. Lauderdale, Florida 3339-1697. E-mail: jkotler@pol.net.

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Appalachian Regional Healthcare is seeking candidates for a Radiation Physicist opportunity available at the 308 bed ARH Regional Medical Center complex located in Hazard, KY.

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An outstanding compensation package will be offered including a very attractive salary range and benefits which include fully paid family plan health insurance, paid vacation, holiday and sick leaves, etc. Interview expenses are assumed by ARH and a relocation allowance is available. For additional information, please forward resume to or contact: Marilyn Hamblin, ARH Corporate Personnel Division, PO Box 8086, Lexington, KY 40533; FAX: 606-226-2586; call 1-800-888-7045 Ext. 532 or e-mail to: mhamblin@arh.org EOE

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Marshfield Clinic, one of the nation's most respected and recognized integrated health care systems is seeking to replace a retiring nuclear medicine physician. We desire a BC/BE radiologist, fellowship

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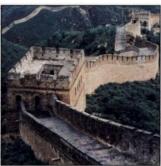


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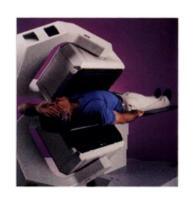


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