No One Comes Closer.

Clinical Excellence

It's simple. The closer you get, the sharper the image...the more you see. Improved clinical accuracy. After all, isn't that what it's all about?

Up close and accurate. At ½” (2.5 mm), the E.CAM pallet is about twenty times thinner than other beds. That means the E.CAM detectors are 2” (50 mm) closer to the patient for every procedure.

Special infrared positioners are located right on each detector's surface, automatically bringing the camera as close to the patient as possible for every whole body, 180° and 90° SPECT imaging procedure...resolving the smallest of details.

Thanks to a new design process that took the best ideas from customers around the world—and made them a reality. The E.CAM is unlike any other system—and it's available today.

E.CAM™ ultra-thin patient pallet

E.CAM™ ultra-thin patient pallet

Conventional carbon fiber pallet
If nuclear medicine is constantly changing, shouldn’t your thyroid uptake system be able to keep up?

Imagine buying a thyroid uptake system that’s built to last...and to adapt.

The CAPTUS® 2000 offers the most advanced capabilities from subtracting a predose measurement, counting a single capsule and multiplying by the number given, to measuring residual liquid activity in a vial after the dose is given. Design innovations such as the spring arm stand and automated constancy tests make it easier and faster to use.

But the most powerful advantage of the CAPTUS® 2000 is in its Intel® Pentium® Processor and familiar Microsoft Windows® based software. As new procedures are developed, they can be programmed into the software with the insertion of a disk. Introducing a new technique doesn’t require a new equipment purchase.

The CAPTUS® 2000: built for high performance today...and tomorrow.
It’s better under stress

The value of cardiac imaging lies in the accuracy of stress perfusion images. And that’s where Cardiolite® comes through.

With Cardiolite, you can simultaneously obtain stress perfusion and resting function (gated stress Cardiolite study)—that’s critical diagnostic information regarding cardiac perfusion, wall motion, wall thickening, and LVEF—all of which can help with patient management decisions. And, for patients unable to achieve adequate levels of stress through exercise, imaging results can be optimized by using pharmacologic agents such as I.V. Persantine® (dipyridamole USP).

To enhance patient management, find out about the advantages of stress Cardiolite before you order your next study.

By performing stress Cardiolite studies you can...
- Accurately diagnose CAD
- Risk stratify patients with known or suspected CAD
- Reduce equivocal interpretation in difficult-to-image patients (women, obese, and large-chested)
- Acquire stress perfusion and resting function information
- Improve patient management decisions, which may reduce costs

Cardiolite®
Kit for the preparation of Technetium Tc99m Sestamibi

To reduce the uncertainty
Cardiolite comes through

© 1996, DuPont Pharma

Stress testing should be performed only under the supervision of a qualified physician in a laboratory equipped with appropriate resuscitation and support apparatus. There have been infrequent reports of signs and symptoms consistent with seizure and severe hypersensitivity after administration of Tc99m Sestamibi. Pharmacologic stress may be associated with serious adverse events such as myocardial infarction, arrhythmias, hypertension, bronchoconstriction, and cerebrovascular events. Caution should be used when pharmacologic stress is selected as an alternative to exercise.

Persantine® is a registered trademark of Boehringer Ingelheim International GmbH. I.V. Persantine® is manufactured and distributed by DuPont Pharma under license from Boehringer Ingelheim Pharmaceuticals, Inc.

Please see brief summary of prescribing information on adjacent page.
Summary

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:

- Dyspnea: 35%
- Chest Pain: 19%
- ST segment depression: 19%
- Arhythmias: 15%

Cardiogram, Metageneus, Impairment of Fertility

In comparison with most other diagnostic technetium labeled radiopharmaceuticals, the radiation dose to the ovaries (1.5mrad/10mCi at rest, 1.2 mrad/10mCi at exercise) is high. Minimal exposure (ALARA) is necessary in women of childbearing capability. (See Dosimetry subsection in DOSES AND ADMINISTRATION.)

The activatable (CoMEX1)BIF2 was evaluated for genetic potential in a battery of the tests. No genetic potential was observed in the tests of chromosome analysis (CoMEX1)BIF2 did not show genotoxic effects in vivo mouse micronucleus test at a dose which caused systemic and bone marrow toxicity (Singh, et al. 600 x 0.60 x normal 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 Sestamibi is excreted in human milk during lactation. It is not known whether Technetium Tc99m Sestamibi is excreted in human milk. Therefore, breast feeding should be substituted for breast feeding.

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 transient perioral and/or taste perversion (metallic or bitter taste) immediately after the injection of Technetium Sestamibi. A few cases of transient chest pain, diaphoresis, syncope, and other cardiovascular events have been reported. A few patients have experienced in the past few cases of cutaneous disorders, including rash, urticaria, and angioedema. These cutaneous reactions were infrequent and were observed only at the injection site. Other systemic reactions occurring within 2 hours after the injection of Technetium Tc99m Sestamibi are described above (see WARNINGS).

In a study of 111 patients, the most frequent adverse reactions were: chest pain (5.7%), perioral or taste perversion (2.6%), and fatigue (2.6%). Other reactions included hypotension and dyspnea (0.9%), vomiting (1.8%), and chest pain (1.8%). In a study of 40 patients, the most frequent adverse reactions were: chest pain (4.5%), perioral or taste perversion (1.3%), and fatigue (1.3%). Other reactions included dyspnea (1.3%), hypotension (1.3%), and rash (1.3%).

Less common adverse events occurring in 1% of patients were: chest pain (0.9%), perioral or taste perversion (0.9%), fatigue (0.9%), hypotension (0.9%), chest pain (0.9%), perioral or taste perversion (0.9%), hand blanching not specified (0.8%), chest pain (0.8%), dyspnea (0.8%), fatigue (0.8%), chest pain (0.8%), headache (0.6%), and nausea (0.6%).

Central and Peripheral Nervous System: Hypotension (0.5%), hypotension (0.5%), hypoesthesia (0.5%), paresthesia (0.5%), headache (0.5%), and dyspnea (0.5%).

Gastrointestinal System: Diarrhea (0.1%), nausea (0.1%), vomiting (0.1%), unspecified (0.1%), diarrhea (0.1%), unspecified (0.1%), and nausea (0.1%).

Respiratory System: Pharyngitis (0.5%), bronchitis (0.2%), unspecified (0.1%), and unspecified (0.1%).

Other: Myalgia (0.9%), back pain (0.6%), injection site reaction unspecified (0.4%), dysphoria (0.4%), and myalgia (0.4%).

Because animal reproduction studies are not always predictive of human responses, this drug should be used during pregnancy only if clearly needed.

*Calculation based on assumed body weight of 50 kg.

Nursing Mothers: Dipyridamole is excreted in human milk.

Pediatric Use: Safety and effectiveness in the pediatric population have not been established.

ADVERSE REACTIONS: Adverse reaction information concerning intravenous Persantine® (dipyridamole USP) is derived from clinical trials in which a study of 511 patients in which intravenous Persantine® was used as an adiagnostic agent to facilitate myocardial perfusion imaging and from spontaneous reports of adverse reactions and the published literature.

Serious adverse events (cardiac death, fatal and non-fatal myocardial infarction, ventricular fibrillation, asystole, sinus arrest, ventricular arrhythmias, and other arrhythmias) have been reported. There have been cases involving death, and some of these cases involved patients who had a history of asthma. When asthma is present, the risk of unpredictable and severe asthma reactions is increased. In patients with a history of asthma, it is recommended not to use this drug for prophylaxis or treatment of cardiac disease.

In a study of 311 patients, the most frequent adverse reactions were: chest pain (2.6%), perioral or taste perversion (2.6%), and fatigue (2.6%). Other reactions included hypotension and dyspnea (0.9%), vomiting (1.8%), and chest pain (1.8%). In a study of 40 patients, the most frequent adverse reactions were: chest pain (4.5%), perioral or taste perversion (1.3%), and fatigue (1.3%). Other reactions included dyspnea (1.3%), hypotension (1.3%), and rash (1.3%).

Less common adverse events occurring in 1% of patients were: chest pain (0.9%), perioral or taste perversion (0.9%), fatigue (0.9%), hypotension (0.9%), chest pain (0.9%), perioral or taste perversion (0.9%), hand blanching not specified (0.8%), chest pain (0.8%), dyspnea (0.8%), fatigue (0.8%), chest pain (0.8%), headache (0.6%), and nausea (0.6%).

Central and Peripheral Nervous System: Hypotension (0.5%), hypotension (0.5%), hypoesthesia (0.5%), paresthesia (0.5%), headache (0.5%), and dyspnea (0.5%).

Gastrointestinal System: Diarrhea (0.1%), nausea (0.1%), vomiting (0.1%), unspecified (0.1%), diarrhea (0.1%), unspecified (0.1%), and nausea (0.1%).

Respiratory System: Pharyngitis (0.5%), bronchitis (0.2%), unspecified (0.1%), and unspecified (0.1%).

Other: Myalgia (0.9%), back pain (0.6%), injection site reaction unspecified (0.4%), dysphoria (0.4%), and myalgia (0.4%).

Because animal reproduction studies are not always predictive of human responses, this drug should be used during pregnancy only if clearly needed.
For postprostatectomy patients with rising PSA and a negative or equivocal standard metastatic evaluation in whom there is a high clinical suspicion of occult metastatic disease.

**NEW**

**PROSTASCINT™**

Kit for the Preparation of Indium In 111 Capromab Pendetide

A Clearer View

For Clearer Decisions

In Prostate Cancer Management

* For full indications for use of ProstaScint, please refer to the prescribing information.
† As with other tests to evaluate prostate cancer, information provided by ProstaScint imaging should be considered in conjunction with other diagnostic information.

ProstaScint and Partners in Excellence (PIE) are trademarks of CYTOGEN Corporation.
Please see brief summary of prescribing information on adjacent page.
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For more information, please call the CYTOGEN Customer Service Hotline at 1-800-833-3533 or you can find us on the world-wide web at http://cytogen.com/prostasc.html
The first prostate cancer targeted imaging agent

- Provides prognostic information in high-risk patients that complements PSA, Gleason score, and pathological stage.
- Generally well tolerated

Supported by the resources and services of BARD Urological Division and CYTOGEN Corporation to reach the medical community

Partners in Excellence (PIE™): A comprehensive educational program in ProstaScint imaging

- Available only at sites where personnel have been trained in ProstaScint imaging and accredited by the American College of Nuclear Physicians (ACNP)
- ProstaScint scans should be interpreted only by physicians who have had specific training in the interpretation of these images through the Partners in Excellence program, due to the potential for false positive and false negative image interpretations. (See full prescribing information sections WARNINGS and CLINICAL STUDIES.)
**ProstaScint** Kit

*(Capromab Pendetide)*

**Kit for the Preparation of Indium in 111 Capromab Pendetide**

For Intravenous Use Only

**BRIEF SUMMARY**—Consult package insert for full prescribing information

**INDICATIONS AND USAGE** Indium in 111 ProstaScint (Capromab Pendetide) is indicated as a diagnostic imaging agent in men with suspected prostate cancer to be clinically localized after standard diagnostic evaluation (e.g., chest x-ray, bone scan, CT scan, or MRI), who are at high risk for pelvic recurrence of prostate cancer (NACR 2-6). ProstaScint imaging is performed in newly-diagnosed patients. It is not indicated in patients who are not at high risk. Indium in 111 ProstaScint is also indicated as a diagnostic imaging agent in post-prostatectomy or prostate brachytherapy patients with a rising PSA and negative or equivocal standard metabolic evaluation who have a high clinical suspicion of occult metastatic disease. The imaging performance of Indium in 111 ProstaScint following radiation therapy has not been studied. The information provided by Indium in 111 ProstaScint imaging should be considered in conjunction with other diagnostic information. Scares that are positive for metastatic disease should be confirmed histologically in patients who are otherwise candidates for surgery or radiation therapy unless medically contraindicated. Patients that are negative for metastatic disease should not be used in lieu of histological confirmation. ProstaScint is not indicated as a screening tool for carcinoma of the prostate nor for radionuclide therapy for the purpose of assessment of response to treatment.

**CONTRAINDICATIONS** Indium in 111 ProstaScint should not be used in patients who are hypersensitive to this or any other product of murine origin or to Indium 111 chloride.

**WARNINGS** Patient management should not be based on Indium in 111 ProstaScint (Capromab Pendetide) scan results without appropriate confirmatory studies since in the pivotal trials, there was a high rate of false positive and false negative image interpretations (See PRECAUTIONS). Indium in 111 ProstaScint images should be interpreted only by physicians who have had specific training in Indium in 111 ProstaScint image interpretation (see PRECAUTIONS, Imaging Precautions). Vague, nonspecific, or ambiguous, lesions can occur in patients who receive murine antibodies. Although serious reactions of this type have not been observed in clinical trials after Indium in 111 ProstaScint administration, medication of the treatment of hypersensitivity reactions should be available during administration of this agent. Indium in 111 ProstaScint may induce human anti-mouse antibodies which may interfere with some immunoassays, including those used to assay PSA and digoxin (see PRECAUTIONS, Drug/Laboratory Test Interactions).

**PRECAUTIONS**

**General** There were high rates of false positive and false negative image interpretations in the pivotal trials (see Clinical Studies). False positive scan interpretations may result in: (a) inappropriate surgical intervention to confirm scan results, (b) undertreatment of curative therapy if results are not confirmed, or (c) inadequate surgical staging if only areas of uptake are sampled. Surgical sampling should not be limited to the areas of positive uptake, unless histologic examination of these areas is diagnostic. Due to the potential for false negative scan interpretations, negative images should not be used in lieu of histologic confirmation. Proper patient preparation is mandatory to obtain optimal images for interpretation (see Imaging Precautions, below). Bone scans are more sensitive than ProstaScint (Capromab Pendetide) in the detection of metastases to bone, and Indium in 111 ProstaScint should not replace bone scan for the evaluation of skeletal metastases.

**Imaging Precautions** Radioimmunoassays should be used only by physicians and other professionals who are qualified by training and experience in the safe use and handling of radionuclides. Indium in 111 ProstaScint images should be interpreted only by physicians who have had specific training in the interpretation of Indium in 111 ProstaScint images. There may be Indium in 111 ProstaScint clearance and imaging localization observed in the bowel, blood pool, kidney, and urinary bladder. When obtaining all 72-120 hour planar and Single-Photon Emission Computerized Tomography (SPECT) images, the bladder should be catheterized and emptied. The administration of a cathartic is required the evening before imaging the patient, and a cleansing enema should be administered within an hour before the 72-120 hour imaging session. The contents of the kit are not radiotracers. However, after the Indium in 111 chloride is added, appropriate shielding of Indium in 111 ProstaScint must be maintained. Care should be taken to minimize radiation exposure to patients and medical personnel consistent with proper hospital and patient management procedures. Each ProstaScint kit is a unit of use package. The contents of the kit are to be used only to prepare Indium in 111 ProstaScint unless ProstaScint should not be administered directly to the patient. The administration of an imaging session with Indium in 111 chloride. The entire Indium in 111 ProstaScint dose must be administered to the patient for whom it was prescribed. Reduce the dose of Indium in 111, unlabeled ProstaScint or Indium in 111 ProstaScint may adversely impact imaging results and is not recommended. The components of the kit are sterile and pyrogen-free and contain no preservative. Indium in 111 ProstaScint should be used within 8 hours after radiolabeling. It is essential to follow the directions for preparation carefully and to adhere to strict aseptic procedures during the preparation of the radiolabeled product.

**Information for Patients** Murine monoclonal antibodies (MAbs) are foreign proteins, and their administration can induce HAMA. While limited data exist concerning the clinical significance of HAMA, the presence of HAMA may interfere with murine-antibody based immunologic, or could compromise the efficacy of diagnostic or therapeutic murine antibody-based agents and increase the risk of adverse reactions. For these reasons, patients should be informed that the use of this product could adversely affect the future ability to diagnose recurrence of their tumor, the ability to perform certain other laboratory tests, or to use other murine-based products. Patients should be advised to discuss prior use of murine antibody-based products with their physicians (see Heterologous Protein Administration, below).

**Heterologous Protein Administration** Indium in 111 ProstaScint has been shown to induce HAMA to murine IgG, infused after single injection. Infusions with low peak levels after single administration, however, are almost always negative by RIA after single infusion in 8% (203/250) of patients, while 1% of patients had levels greater than 100 ng/ml. In addition, serum HAMA levels were detected by RIA after repeat infusion in 19% (52/272) of the patients. While there is some concern that the clinical significance of HAMA, detectable serum levels can alter the clearance and tissue biodistribution of MAbs. Development of persistently elevated serum HAMA levels could compromise the efficacy of diagnostic or therapeutic murine antibody-based agents. In repeat administration trials, 93% (65/70) of the evaluable repeat infusions were assessed for normal tissue biodistribution of the MAb conjugates. Pre-infusion serum HAMA levels were generally not predictive of altered distribution. When considering the administration of Indium in 111 ProstaScint to patients who have previously received other murine antibody-based products, physicians should be aware of the potential for assay interference and increased clearance and altered biodistribution, which may interfere with the quality or sensitivity of the imaging study. Prior to administration of murine antibodies, including Indium in 111 ProstaScint, the physician should review the patient history to determine whether the patient has previously received such products.

**Drug Interactions** The effect of surgical and/or medical androgen ablation on the imaging performance of Indium in 111 ProstaScint has not been studied. Preliminary data suggest hormone ablation may increase PSA expression, with concurrent decrease in tumor expression of PSA. The use of ProstaScint in this patient population cannot be recommended at this time.

**Drug/Laboratory Test Interactions** The presence of HAMA in serum as a result of ProstaScint may interfere with some antibody-based immunosassays (such as PSA and digoxin). When this interaction occurs result in likelihood to increase. When following PSA levels, assay methods resistant to HAMA interference should be utilized. PSA assays which are found to be resistant to HAMA interference are Hybritech Tandem-R and Abbott RIA. When patients have received other ProstaScint the clinical laboratory should be notified to take appropriate measures to avoid interference by HAMA with clinical laboratory testing procedures. These methods include the use of non-murine-based immunosassays, HAMA removal by adsorption, or sample pre-treatment to block HAMA activity.

**Cardiac Patients, Hemodynamically Impaired or Failing** Long-term animal studies have not been performed to evaluate the cardiogenic or hemodynamic potential of Indium in 111 ProstaScint or to evaluate its effect on longevity.

**Pregnancy** ProstaScint is not indicated for use in women.

**Nursing Mothers and/or Lactating Women** ProstaScint is not indicated for use in women.

**Pediatric Use** The safety and effectiveness of Indium in 111 ProstaScint in pediatric patients have not been established. ProstaScint is not indicated for use in children.

**ADVERSE REACTIONS** ProstaScint (Capromab Pendetide) was generally well tolerated in the clinical trials. After administration of single doses of Indium in 111 ProstaScint, adverse reactions were observed in 4% of patients. The most common reported adverse reactions were headache, hypotension, and hypertension, which occurred in 1% of patients. Elevated liver enzymes and injection site reactions occurred in slightly less than 1% of patients. The adverse reactions, listed in order of decreasing frequency were pruritus, fever, rash, nausea, vomiting, dysuria, incontinence, breathlessness, flushing, lightheadedness, asthma, burning sensation in the throat, shortness of breath, and alteration of taste. Most adverse reactions were mild and rapidly resolved. Data from repeat administration in 61 patients revealed a similar incidence of adverse reactions (5%). No deaths were attributable to Indium in 111 ProstaScint administration.


ProstaScint (Capromab Pendetide) is covered in whole or in part by at least the following US patents: 4,871,958, 4,741,500, and 5,162,504.

CYTOGEN Corporation
Princeton, NJ 08540-5308

Help fight lung cancer the Christmas Seal People

It's a matter of life and breath

Space contributed by the publisher as a public service
Positron Imaging in Clinical Oncology

ICP/SNM Seminar
Tuesday, June 3, 1997  5:00-8:00 pm
Hilton Palacio del Rio
200 South Alamo Street
San Antonio, Texas

Course Outline
Imaging instrumentation, radiopharmaceutical delivery, clinical applications and reimbursement for positron imaging are rapidly changing. This course will provide an up-to-date perspective on the expansion of positron imaging technologies to include high energy collimation, dual head gamma cameras with coincidence detection, partial ring PET scanners and high end PET systems. The components of a radiopharmacy network that supplies FDG to clinics will be described. The clinical questions will be exemplified in the course by focusing on detection, staging and therapeutic assessment of various cancers with these positron imaging systems. Data from clinical trials, formulated into evidence based cost benefit analysis, will be presented along with an update on the status of reimbursement from various types of private and federal sources.

Program
5:00-5:05  Welcome  Peter E. Valk, M.D.
5:05-5:25  Positron Imaging Technology – Present and Future  Michael E. Phelps, Ph.D.
5:25-6:25  PET Imaging in Clinical Oncology  R. Edward Coleman, M.D.
Solitary Pulmonary Nodules and Non-Small Cell Lung Cancer
Recurrent Colorectal Cancer  Peter E. Valk, M.D
Metastatic Melanoma  Richard L. Wahl, M.D.
Breast Cancer and Lymphoma  Carter Young, M.D.
Head and Neck Cancer and Cancer of the Esophagus  Val J. Lowe, M.D.
6:25-6:40  BREAK
6:40-7:10  Scintillation Camera FDG Imaging in Oncology  Martin P. Sandler, M.D.
Cancer of the Lung and Colon  Paul D. Shreve, M.D.
Cancer of the Lung, Esophagus and Head and Neck
7:10-7:20  Availability and Delivery of FDG  Bradley Holmgren
7:20-7:35  Cost Benefit Analysis for Oncological Positron Imaging  Sanjiv S. Gambhir, M.D., Ph.D.
7:35-7:45  Reimbursement for Oncological Positron Imaging  Ruth Dean Tesar
7:45-8:00  Discussion
Join more than 8000 of your colleagues in celebrating the 44th Annual Meeting of the Society of Nuclear Medicine in San Antonio, Texas, June 1-5, 1997. Participate in the intensive educational program, review posters, discuss the most recent developments with colleagues and join any of a host of much talked about extracurricular activities. Don’t miss this opportunity to learn, mingle with your colleagues, and visit with exhibitors.

**Continuing Education Courses**

Refresher and state-of-the art continuing education courses in chemistry, physics, quality assurance, cardiovascular nuclear medicine, PET, SPECT and NMR will supply up-to-the minute approaches and procedures for all clinical settings.

**Scientific Papers**

This year’s presentation of over 1200 scientific papers and posters includes a distillation of the latest advancements and finest work achieved by outstanding scientists and physicians in the field of nuclear medicine. These papers, presented by the original authors, with over 30 subjects to choose from, will provide a unique opportunity for enhancing your knowledge or exploring new avenues in correlative areas of nuclear medicine. Ample time is allotted at these presentations for questions and discussions. An extensive display of scientific posters and exhibits will augment the presentations.

The ever-increasing importance of the role of nuclear medicine technologist will be explored in our Technologist Program, and over 150 hours of clinical updates will provide chief and staff technologists with the latest in basic, intermediate and advanced studies. This program will broaden expertise and enhance the technologist’s contribution to nuclear medicine.

**Exhibit**

All the major manufacturers of nuclear medicine products and services, more than 100 in all, will be on hand to explain and demonstrate the most technologically advanced equipment. Several companies will present User Meetings to give an in-depth understanding of their products.

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Never before has it been so cost effective and space liberating to have this information at your fingertips.

For those without CD capability, we have made the index available for purchase. You can then use your own journals for reference. Special rates for students.

Minimum System Requirements: Windows 3.1, '95, or NT; 486/33 processor; 11mb hard disk space and 8mb memory; 2x CD-ROM; color monitor displaying at 600x800 with 16 colors (a higher resolution and greater color capability will improve image quality).

DIGITAL PUBLISHING, INC

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1-703-925-0300
Introducing a view from the heart.

MYVIEW™
Technetium Tc99m Tetrofosmin for Injection

A clear view.
- Technetium – labeled
- Rapid and sustained myocardial uptake, with images available from 15 minutes to 4 hours post-injection
- Rapid GI clearance

A convenient view.
- Room temperature preparation, and 8 hour reconstituted shelf-life
- No redistribution
- Available in unit dose

An efficient view.
- Flexible scheduling
- Assessment of myocardial perfusion and ventricular function with a single injection
- Sensitive and reliable detection of coronary disease

A patient’s view.
- Low-radiation exposure compared to other myocardial perfusion agents
- Less than 1% of patients experienced side effects in clinical trials of 764 adults.

See brief summary of prescribing information on following page
Brief Summary

MYOVIE View®

Kit for the Preparation of Technetium Tc99m Tetrofosmin for injection

Diagnostic radiopharmaceutical For intravenous use only

Code H166A

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 pre-dispersed, sterile, non-pyrogenic, lyophilized mixture of 0.23 mg tetrofosmin, 6,8-bis(2-ethoxyethyl)-3,12-dioxa-6,12-diphospho-tetradecane, 30 µg stannous chloride dihydrate (minimum stannous tin 5.0 µg; maximum total stannous and stannic tin 15.8 µg), 0.32 mg sodium hydroxide and 1.0 mg sodium D-glucosinate, 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 pertechnete 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 asymptomatic 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 55-74 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 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 professional 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 determined 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 sulphonolasaiclyte 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 Pertechnete 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 26-94 years). The subjects received a mean dose of 7.67 MBq on the first injection and 22.4 MBq 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. No deaths were observed among the 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 Points

Gastrointestinal: vomiting, abdominal discomfort

Hypersensitivity: cutaneous allergy, hypotension, dyspepsia

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.

DOSEAGE AND ADMINISTRATION

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

- The first dose of 5-6 mCi (185-296 MBq) is given at peak exercise.
- The second dose of 15-24 mCi (555-888 MBq) is given approximately 4 hours later, at rest.

Imaging may begin 15 minutes following administration of the agent.

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

RADIATION DOSEMETRY

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)

<table>
<thead>
<tr>
<th>Target Organ</th>
<th>Exercise</th>
<th>Rest</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gall bladder wall</td>
<td>0.123</td>
<td>0.180</td>
</tr>
<tr>
<td>Upper large intestine</td>
<td>0.075</td>
<td>0.113</td>
</tr>
<tr>
<td>Bladder wall</td>
<td>0.058</td>
<td>0.071</td>
</tr>
<tr>
<td>Large intestine</td>
<td>0.057</td>
<td>0.082</td>
</tr>
<tr>
<td>Small intestine</td>
<td>0.045</td>
<td>0.063</td>
</tr>
<tr>
<td>Kidney</td>
<td>0.039</td>
<td>0.046</td>
</tr>
<tr>
<td>Salivary glands</td>
<td>0.080</td>
<td>0.043</td>
</tr>
<tr>
<td>Ovaries</td>
<td>0.029</td>
<td>0.035</td>
</tr>
<tr>
<td>Uterus</td>
<td>0.027</td>
<td>0.031</td>
</tr>
<tr>
<td>Bone surface</td>
<td>0.023</td>
<td>0.021</td>
</tr>
<tr>
<td>Pancreas</td>
<td>0.019</td>
<td>0.018</td>
</tr>
<tr>
<td>Stomach</td>
<td>0.017</td>
<td>0.016</td>
</tr>
<tr>
<td>Thymus</td>
<td>0.016</td>
<td>0.022</td>
</tr>
<tr>
<td>Adrenals</td>
<td>0.016</td>
<td>0.015</td>
</tr>
<tr>
<td>Heart wall</td>
<td>0.015</td>
<td>0.015</td>
</tr>
<tr>
<td>Red marrow</td>
<td>0.015</td>
<td>0.014</td>
</tr>
<tr>
<td>Spleen</td>
<td>0.015</td>
<td>0.014</td>
</tr>
<tr>
<td>Muscle</td>
<td>0.013</td>
<td>0.012</td>
</tr>
<tr>
<td>Testes</td>
<td>0.013</td>
<td>0.011</td>
</tr>
<tr>
<td>Liver</td>
<td>0.012</td>
<td>0.015</td>
</tr>
<tr>
<td>Thyroid</td>
<td>0.012</td>
<td>0.011</td>
</tr>
<tr>
<td>Bladder</td>
<td>0.010</td>
<td>0.008</td>
</tr>
<tr>
<td>Skin</td>
<td>0.008</td>
<td>0.007</td>
</tr>
<tr>
<td>Breasts</td>
<td>0.008</td>
<td>0.007</td>
</tr>
</tbody>
</table>

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 x 10^{-4} mSv/MBq and 1.12 x 10^{-4} mSv/MBq after exercise and rest respectively.

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