The New Measure of Performance.

From around the world. **WE LISTENED TO YOU.** Lots of you.
We looked at the whole picture. Through your eyes.

With purpose, we set our sights on a new standard in camera flexibility.
**IMAGING YOUR PATIENTS.** Every one of them. For any nuclear procedure.

Using your vision, we expanded the clinical possibilities.
At any energy. **BEYOND SPECT.** Well beyond.

We reached into a new dimension.
And found the future. **EMISSION TOMOGRAPHY**
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.
A *breakthrough*

in clinical imaging

is happening.

*One patient at a time.*
CORONAL VIEW OF PATIENT with lung cancer. MCD scan revealed abnormal uptake of FDG, showing primary tumor and metastatic disease.

TRANSVERSE VIEW OF PATIENT with epilepsy. MCD scan revealed decreased activity of FDG in right lobe.

CORONAL VIEW OF PATIENT with esophageal cancer. MCD scan revealed abnormal uptake of FDG in the neck correlating with PET and CT scans.
Asymptomatic.
Rising CEA.
2 years post-op for colorectal cancer.
CT is equivocal.

Now there's a new way to determine resectability.
CEA-Scan is a new imaging agent that enhances your pre-operative determination of colorectal cancer resectability. CEA-Scan is indicated, in conjunction with standard diagnostic evaluations, for detection of the presence, location and extent of recurrent and/or metastatic colorectal carcinoma involving the liver, extrahepatic abdomen and pelvis in patients with a histologically confirmed diagnosis of colorectal carcinoma.

Surgery confirms that CEA-Scan with CT can help you make decisions concerning surgical resectability. Compared to CT alone, CEA-Scan with CT:

- Identified 59/89 versus 42/89 patients with resectable disease, a 40% increase in detection rate
- Identified 34/73 versus 14/73 patients with non-resectable disease, or more than twice as many
- In patients with negative or equivocal CT (occult disease), reduced the number of false-negative patients from 59 to 23, a 60% decrease.1

CEA-Scan has a 97% positive predictive value for lesions when concordant with CT (146 true-positive lesions versus 4 false-positives).
SENSITIVE, SAME-DAY IMAGING

CEA-Scan enables improved colorectal cancer detection compared to standard diagnostic methods (SDM, 95% of which were CT).

- In general, CEA-Scan was more sensitive and less specific in the abdomen and pelvis than CT.
- However, direct comparisons of the performance characteristics of SDM to CEA-Scan are difficult to interpret, since the results of SDM were entry criteria for both Phase 3 protocols.

ADVANCED TECHNOLOGY

CEA-Scan offers the advantages of Fab' fragment design.

- Short biological half-life (13±4 hours) and rapid blood clearance improve tumor-to-background ratios.
- Minimal liver metabolism allows hepatic imaging.
- Small fragment size enhances renal clearance.
- Fragment technology provides lower immunogenicity.

ESTABLISHED SAFETY PROFILE

Over 400 patients who have received CEA-Scan have been evaluated for human anti-mouse antibody (HAMA).

- <1% showed an elevation of HAMA levels.
- Limited data are available regarding the safety of re-administration.

In the patients studied with CEA-Scan, one patient each developed the following minor self-limiting adverse effects: transient eosinophilia, nausea, bursitis, urticaria, generalized itching, headache, upset stomach and fever. Out of a total of over 500 patients receiving the product to date, there has been a single report of an apparent grand mal epileptic seizure in a severely hypertensive patient that was "possibly related" to CEA-Scan infusion.

HELPING YOU MAKE DECISIONS ABOUT TUMOR RESECTABILITY

Manufactured by: IMMUNOMEDICS, INC.

Distributed by: MALLINCKRODT MEDICAL

Please see adjacent page for brief summary of prescribing information

References:
For the Preparation of Technetium Tc 99m Arcitumomab.
Sterile, Non-Pyrogenic, Lyophilized Powder for Intravenous Use Only.

DESCRIPTION

CEA-Scan® (Arcitumomab) is a radiodiagnostic agent consisting of a murine monoclonal antibody Fab' fragment, arcitumomab, formulated to be labeled with 99mTc-Technetium [99mTc-Tc]. The active component, arcitumomab, is a Fab' fragment generated from IMMU-4-1, a murine IgG1 monoclonal antibody produced in murine ascitic fluid supplied to Immunomedics, by Charles River Laboratories. IMMU-4-1 is purified from the ascitic fluid and is digested with papain to produce Fab' (a fragment) and subsequently reduced to produce the 50,000-dalton arcitumomab. Each vial contains the non-radioactive materials necessary to prepare one patient dose. CEA-Scan® is a sterile, lyophilized formulation, containing 1.25 mg of arcitumomab and 0.29 mg strontium per vial, with potassium sodium tartrate tetrahydrate, sodium acetate trihydrate, sodium chloride, acetic acid, glacial, hydrochloric acid, and sucrose. The imaging agent, technetium Tc 99m CEA-Scan®, technetium Tc 99m arcitumomab, is formed by reconstitution of the contents of the CEA-Scan® vial with 30 mL of 0.9% sodium chloride in 1 mL of Sodium Chloride for injection, USP. The resulting solution is pH 5.7 for injection. Following administration, the labeled antibody can be visualized by common nuclear medicine instrumentation.

INDICATIONS

CEA-Scan® (Arcitumomab) is indicated, in conjunction with standard diagnostic evaluations (e.g., additional imaging procedures, biopsy, laparotomy and/or surgical resection) and extent of recurrent and/or metastatic colorectal carcinoma involving the liver, extraperitoneal abdomen and pelvis in patients with a histologically confirmed diagnosis of colorectal carcinoma. CEA-Scan® provides additional information in patients with no evidence of disease by standard diagnostic modalities (SDM) in whom recurrence or metastasis is suspected based upon elevated or rising serum CEA, and in patients with evidence of metastatic or recurrent disease on SDM. A retrospective analysis suggests that these data can be useful in the evaluation of patients in whom surgical intervention (biopsy, exploratory laparotomy and/or surgical resection) is under consideration.

CEA-Scan® is not indicated for the differential diagnosis of suspected colorectal carcinoma or as a screening tool for colorectal cancer. CEA-Scan® is not intended for readministration or for assessment of response to treatment (see PRECAUTIONS).

CONTRAINDICATIONS

CEA-Scan® should not be administered to patients who are hypersensitive to products of murine origin or to Technetium [Tc-99m].

WARNINGs

Anaphylactic and other hypersensitivity reactions can occur following administration of mouse protein to patients. Although serious reactions of these types have not been observed in clinical trials after CEA-Scan® administration, medications for the treatment of hypersensitivity reactions, e.g., epinephrine, antihistamines and corticosteroids, should be available for immediate use in the event of an anaphylactic reaction during administration of this agent.

PRECAUTIONS

General

CEA-Scan® is to be interpreted in conjunction with standard diagnostic modalities. A negative or positive CEA-Scan® by itself should not be utilized in the diagnostic evaluation of colorectal cancer. Discordant results are substantially less predictive than concordant results.

CEA-Scan® should not be used as a screening test for colorectal cancer.

Limited data are available regarding the safety of readministration.1 There are no data to support the efficacy of CEA-Scan® readministration. CEA-Scan® should be used only once in a patient.

The components of CEA-Scan® are sterile and non-pyrogenic. It is essential to follow preparation directions carefully and to adhere to strict aseptic procedures during preparation of CEA-Scan® [99mTc]. The contents of the vial are intended only for use in the preparation of CEA-Scan® [99mTc] and are not to be administered directly to patients.

The contents of the vial before preparation are not radioactive. However, after the 99mTc-Tc-pertechnetate is added, adequate shielding of the preparation must be maintained. Appropriate safety measures should be used to minimize occupational and environmental exposure to patients, consistent with proper patient management.

Radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radiocadioa.

Imaging Interpretation

General

There are limited data to determine the imaging characteristics and efficacy of the CEA-Scan® (Arcitumomab) in detection of lesions outside of the abdominopelvic cavity.22

Areas of potential false-positive readings, particularly with planar imaging, may be observed near the major blood pools (heart, major vessels, etc.) at very early imaging times, near the sites of antibody fragment metabolism (kidneys and urinary bladder), and in the intestines and gallbladder. Late imaging may also aid in the evaluation of suspected normal bowel activity.

With regard to imaging of tumor near the kidneys or urinary bladder, it is advisable to have the patient void prior to accumulation of imaging data to decrease bladder activity. Careful SPECT imaging near the kidneys and bladder has been helpful.

Porta Hepatis Region

Precise localization of lesions in the region of the porta hepatis has been difficult. Lesions within the porta hepatis region may be present within the liver or portal vessels, at the site of surgical exploration, such lesions (which if nodal would preclude resection of hepatic metastases) should be explored first.

False-Positive Lesions

There were 52 false-positive lesions observed in 41 patients from a total of 209 surgically explored subjects in the two pivotal trials. Thirty-five of these lesions were in occult disease patients. Of the 52 false-positive lesions, 11 were observed in the liver, 17 in the extra-hepatic abdomen, and 24 in the pelvis. A pathological correlation to the lesions was infrequently documented; these included granulomas in the liver (1 instance), adhesions with or without subureter granulomas (4 cases), surgical incision site (1 case). Descriptions of false-positive lesions within the abdomen were suggestive of colonic activity in several cases.

Hot-Rimmed, and Cold Lesions

Only hot or rimmed lesions should be considered as positive for tumor. Lesions that are rimmed or cold usually fall in as hot or rimmed, respectively, with 1.25 mm. Often, large lesions, due to pre-existing colonic or central necrosis, will appear to be cold.

Information for Patients

Murine monoclonal antibodies are foreign proteins, and their administration can induce human anti-mouse antibodies (HAMA). While limited data exist concerning the clinical significance of HAMA, the presence of HAMA may interfere with murine antibody-based immunomassays (e.g., serum CEA assays), could compromise the efficacy of in vitro or in vivo diagnostic or therapeutic murine antibody-based agents, and may increase the risk of adverse reactions. For these reasons, patients should be informed that the use of this product could affect the future use of other murine-based products, including CEA-Scan®, and they should be advised to discuss prior use of murine-based antibody products with their physicians. (see Heterologous Protein Administration)

Heterologous Protein Administration

The presence of HAMA and human anti-mouse fragment antibodies have been reported in patients before and after receiving CEA-Scan® (<1% of patients develop HAMA to the antibody fragment). While hypersensitivity reactions to CEA-Scan® have not been observed to date, it is possible that such reactions could occur, resulting in anaphylactic shock, serum sickness or death. In addition, patients who have previously received murine monoclonal antibody products are more likely to have HAMA. When considering the use of the CEA-Scan® in immunocompromised patients who have previously received murine antibody-based products, physicians should be aware of the potential for HAMA to increase the risk of allergic reactions and to alter clearance and biodistribution. The quality or sensitivity of the imaging study may then be compromised.

Drug/Laboratory Test Interactions

The presence of HAMA in serum may interfere with two-site murine antibody-based immunomassays, such as assays trans-CA and CA-125. If HAMA is known or suspected to be present, the clinical laboratory should be notified that interference may occur.

CEA-Scan® may interfere with serum assays for assessment of serum levels of CEA. Therefore, any determina

REFERENCES


2. Data on File at Immunomedics, Inc.


Immunomedics, Inc.

300 American Road
Monroe Plains, NJ 07560

Manufactured by:

Distributed by:

©1996 Mallinckrodt Medical, Inc.

M22622

9/96

Printed in U.S.A.
Nuclear medicine's future depends upon its ability to better detect and treat disease. So you have a stake in the future of CEA-Scan® (Arcitumomab), a new radiodiagnostic agent for detection and staging of recurrent and metastatic colorectal cancer.

CEA-Scan is the first Tc99m-labeled antibody. The first antibody fragment. The first same-day antibody fragment imaging agent. The first antibody fragment diagnostic agent with the ability to detect liver metastases. And the first with virtually no immunogenicity (less than 1%).

With CEA-Scan and CT, you can help oncologists and surgeons better evaluate the 600,000 Americans who’ve undergone laparotomy for colorectal cancer. You can better detect lesions which, if excised, make surgical cure possible. Conversely, CEA-Scan and CT can detect otherwise occult disease that can make such resection useless.

Soon, we’ll be introducing additional products for the diagnosis and treatment of other diseases, providing truly new capabilities for nuclear medicine, and those who practice it.
The Society of Nuclear Medicine Invites You to Attend the 44th Annual Meeting in San Antonio, Texas, June 1-5, 1997.

Mark your calendar now! The Annual Meeting Preview will be mailed to you in January, 1997. If you have questions, please contact the SNM Department: Meeting Services. (703) 708-9000 x-229 or fax (703) 709-9274. SNMs home page: http://WWW.SNM.ORG
Introducing a view from the heart.

MYOVIE

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.

Amersham HEALTHCARE

See brief summary of prescribing information on following page
Pregnancy Category C
Animal reproduction studies have not been conducted with Myoview. It is not known whether Myoview can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Therefore, Myoview should not be administered to a pregnant woman unless the potential benefit justifies the potential risk to the fetus.

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

Pediatric Use
Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS
Adverse events were evaluated in clinical trials of 764 adults (511 men and 253 women) with a mean age of 58.7 years (range 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. After Myoview injection, serious episodes of angina occurred in 3 patients. Overall cardiac adverse events occurred in 5/764 (less than 1%) of patients after Myoview injection.

The following events were noted in less than 1% of patients:
- Cardiovascular: angina, hypertension, Torsades de Points
- Gastrointestinal: vomiting, abdominal discomfort
- Hypersensitivity: cutaneous allergy, hypotension, dyspnea
- Special Senses: metallic taste, burning of the mouth, smelling something

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

DOSAGE AND ADMINISTRATION
For exercise and rest imaging, Myoview is administered in two doses:
- The first dose of 5.8 MBq (185-296 MBq) is given at peak exercise.
- The second dose of 15-24 MBq (555-888 MBq) is given approximately 4 hours later, at rest.

Imaging may begin 15 minutes following administration of the agent.

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

RADIATION DOSIMETRY
Based on human data, the absorbed radiation doses to an average human adult (70 kg) from intravenous injections of the agent under exercise and resting conditions are listed in Table 1. The values are listed in descending order as rad/MCi and Gy/MCi and assume urinary bladder emptying at 3.5 hours.

<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>Lower large intestine</td>
<td>0.057</td>
<td>0.082</td>
</tr>
<tr>
<td>Small intestine</td>
<td>0.045</td>
<td>0.063</td>
</tr>
<tr>
<td>Kidney</td>
<td>0.040</td>
<td>0.046</td>
</tr>
<tr>
<td>Salivary glands</td>
<td>0.030</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>Thyroid</td>
<td>0.016</td>
<td>0.022</td>
</tr>
<tr>
<td>Adrenals</td>
<td>0.015</td>
<td>0.021</td>
</tr>
<tr>
<td>Heart wall</td>
<td>0.015</td>
<td>0.014</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>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>Thymus</td>
<td>0.012</td>
<td>0.009</td>
</tr>
<tr>
<td>Brain</td>
<td>0.010</td>
<td>0.008</td>
</tr>
<tr>
<td>Skin</td>
<td>0.006</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), 1989) and gave values of 8.61 x 10^(-6) mSv/MCi and 1.12 x 10^(-6) mSv/MCi after exercise and rest respectively.

Manufactured by Amersham International plc – Amersham, United Kingdom
Patent No. 5,045,302 (r)

Distributed by:
Medi-Physics, Inc., Amersham Healthcare
2636 S. Clearbrook Dr., Arlington Heights, IL 60005
1-800-633-4123 (Toll Free)
February, 1996
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Example SPECT horizontal long-axis (left), vertical (center) and short axis (right) images of Cardiac Insert with 50% cold defect. Filtered backprojection images acquired with Cardiac Insert mounted in Anthropomorphic Torso Phantom (optionally available) as pictured below.

Cardiac Insert shown separately with Fillable Defect Set. Insert may also be used in Cylindrical and Elliptical Phantoms.

Cardiac Insert shown mounted in Anthropomorphic Torso Phantom Model ECT/TOR/P.

To study the effect of breast attenuation on cardiac images, Breast Attachments large (left) or medium (right) may be used together with the Torso Phantom and Cardiac Insert.

**UNIQUE FEATURES AND APPLICATIONS**

- Assures overall system quality
- Solid and fillable inserts simulate transmural and non-transmural cold and hot abnormalities
- Evaluates cardiac ECT data acquisition protocols and reconstruction methods
- Image interpretation training
- Quantitative evaluation of uniform and nonuniform attenuation and scatter compensation methods
- Evaluate cardiac image contrast, % rms noise and signal/noise ratio.

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Circle Reader Service No. 31
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

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. © 1996, DuPont Pharma
Cardiolyte®
Kit for the preparation of Technetium Tc99m Septamibi

FOR DIAGNOSTIC USE

INDICATIONS AND USAGE: CARDIOLYTE®, Kit for the preparation of Technetium Tc99m Septamibi, is a myocardial perfusion agent that is indicated for detecting coronary artery disease by localizing myocardial ischaemia (perfusion defects) in evaluating myocardial function and detecting information for use in patient management decisions. CARDIOLYTE® evaluation of myocardial ischaemia can be accompanied with rest and exercise 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 an old one.

CONTRAINDICATIONS: None known.

WARNINGS: In studying patients in whom cardiac disease is known or suspected, care should be taken to assure appropriate injection and to establish that the injection was made in accordance with safe, accepted clinical procedures. Infrequently, death has occurred in 2 to 4 hours after Tc99m Septamibi use and is usually associated with exercise stress testing (see PRECAUTIONS).

Pharmacologic stress or the nature of the stress may be associated with serious adverse events such as myocardial infarction, arrhythmias, hyper tension, bronchospasm 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 kit are intended only for use in the preparation of Technetium Tc99m Septamibi and are not to be administered directly to the patient without first undergoing the preparatory procedure.

Radioactive drugs must be handled with care and appropriate safety measures should be used to minimize radiation exposure to clinical personnel. Also, care should be taken to minimize radiation exposure to the patients consistent with patient care requirements.

Contents of the kit before preparation are not radioactive. However, after the Sodium Percystate Tc99m Injection has been added, adequate shielding of the final preparation must be maintained.

The components of the kit are pyrogenic and 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 sterile ion in the reduced state. Hence, Sodium Percystate Tc99m Injection containing oxidized sodium should not be used.

Technetium Tc99m Septamibi should not be used more than six hours after preparation.

Radiologists should be cautious in handling drugs to which they are sensitive and to experience the safe use and handling of radiocides and whose experience and training have been approved by the appropriate government agency authorized to license the use of radiocides.

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

Summary

The most frequent exercise stress test endpoints, which resulted in the termination of the test during controlled Tc99m Septamibi studies (two-thirds were cardiac patients) were:
- Fatigue 50%
- Dyspnea 20%
- Chest Pain 10%
- ST Segment Depression 7%
- Arrhythmias 2%

Cardiogenic, Mitralis, Impairment of Fertility

In comparisons with most other diagnostic technetium labeled radiopharmaceuticals, the radiation dose to the ovaries (1.5(nrad/m²) at rest, 1.2(nrad/m²) at exercise) is high. Minimal exposure (ALARA) is necessary in women of childbearing age. (See Dosage and Administration.)

The active intermediate, [Co(II)MoCl4]4-, was evaluated for genotoxic potential in a battery of five tests. No genotoxic activity was observed in the Ames, CHO/HPRT and sister chromatid exchange tests (at or below). At cytoplasmic lethality (1.5(nrad/m²)), an increase in cell with chromosome abnormalities was observed in the in ovo human lymphocyte assay. [Co(II)MoCl4]4- did not show genotoxic effects in the in ovo mouse micronucleus test at a dose which caused systemic and mouse maternal toxicity (SDMouse > 600 x 1000 human dose).

Animal Reproduction and Toxicology Studies

There have been no studies in pregnancy. Technetium Tc99m Septamibi should be given to a pregnant woman only if clearly needed.

Nursing Mothers

Technetium Tc99m Septamibi is excreted in human milk during lactation. It is not known whether Technetium Tc99m Septamibi is excreted in human milk. Therefore, breast feeding should be disapproved 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 9% of patients experienced a transient palmar and/or plantar taste perversion (metallic or bitter taste) immediately after the injection of Technetium Tc99m Septamibi. A few cases of transient headache, flushing, edema, injection site hemorrhage, nausea, vomiting, pruritis, rash, urticaria, moist, dryness, fever, dizziness, chills, dyspnea, and hypertension have also 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 caused by reactions occurring shortly after administration of the agent; transient ataxia in a wrist, and severe hypotenstion, which was accompanied by dyspnea, hypotension, bradycardia, asthenia and vomiting within two hours after a second injection of Technetium Tc99m Septamibi.

DU PONT
Pharmacuticals

Manufactured by
Du Pont Radiochemicals Division
201 Truddle Cove Road
Billerica, Massachusetts 01821

For ordering, Toll Free: 800-225-1372

Boehringer Ingelheim

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Boehringer Ingelheim Pharmaceuticals, Inc.
Radionuclides Business Unit
Ridgefield, Connecticut 06877

Under license from
Boehringer Ingelheim International GmbH

10 ml vial
Manufactured by
Du Pont Merck Pharma
Aquadilla, Puerto Rico 00674

10 ml ampule
Manufactured by
Du Pont Merck Pharma
Aquadilla, Puerto Rico 00674

In printed U.S.A.
4/95 51313-0495 Brief Summary

Circle Reader Service No. 34

Addendum

1. V. Persantine® (dipyridamole USP) Injection 5mg/ml

Brief Summary of Prescribing Information

INDICATIONS AND USAGE IV Persantine® (dipyridamole USP) is indicated as an alternative to exercise in evaluating myocardial perfusion imaging for the evaluation of coronary artery disease in patients who cannot exercise adequately.

CONTRAINDICATIONS: Hyperreactivity to dipyridamole.

WARNINGS: Serious adverse reactions associated with the administration of intravenous Persantine® (dipyridamole USP) have included cardiac death, fatal and non-fatal myocardial infarction, ventricular fibrillation, symptomatic vascular tachcarthycardia, transient cerebral ischemia and asymptomatic cerebral lesions with no correlation to clinical symptoms. Adverse reactions have been reported in cases of angina, sinus node arrest, sinus node depression and conduction block. Patients with abnormal cardiac impulse manufacture/conduction or severe coronary artery disease may be at increased risk for these events.

In a study of 311 patients given intravenous Persantine® as an adjunct to thallium myocardial perfusion imaging, two types of reactions were observed: 1) minor reactions (no treatment required) (0.1%); 2) major reactions (requiring treatment) (0.4%). Adverse reactions included: nausea (3.4%), headache (0.4%), non-fatal (0.1%) and fatal (0.1%) and 2) six cases of severe bronchospasm (0.2%). The incidence of these serious adverse events were as follows: nausea (0.3%), headache (0.3%), diarrhea (0.3%), vomiting (0.3%), chest pain (0.3%), and bronchospasm (0.2%). Intravenous Persantine® thallium imaging must be weighed against the risk to the patient. Patients with a history of unstable angina or recent myocardial infarction, or severe myocardial ischemia, Patients with a history of asthma may be at a greater risk for bronchospasm during IV Persantine® use.

When thallium myocardial perfusion imaging is performed with intravenous Persantine®, pentagonal amphotropine should be readily available for referring adverse events such as bronchospasm or chest pain. Vital signs should be monitored during, and for 10-15 minutes following, the intravenous infusion of Persantine® and an electrocardiographic tracing should be obtained using at least one chest lead. Should severe chest pain or bronchospasm occur, pentagonal amphotropine may be administered by slow intravenous injection (50-100 mg over 30-60 seconds) in doses ranging from 50 to 250 mg. In the case of severe hypotension, the patient should be placed in a supine position with the head tilted down if necessary, before administration of pentagonal amphotropine. If 250 mg of amphotropine does not relieve chest pain symptoms within a few minutes, additional amphotropine may be administered. If chest pain continues despite use of amphotropine and nitroglycerine, the possibility of myocardial ischemia should be considered. If clinical judgment dictates further observation, an additional one minute delay in the administration of pentagonal amphotropine, thallium-201 may be given and viewed at two minutes for one minute before injection of amphotropine. This will allow initial thallium imaging to be performed before reversion of the pharmacologic effect of Persantine® on the coronary circulation.

PRECAUTIONS See WARNINGS

Drug Interactions: Oral maintenance theophylline and other xantine derivatives such as caffeine may abolish the coronary vasodilating effect induced by intravenous Persantine® (dipyridamole USP) administration. This could lead to a false negative thallium imaging result (see Mechanism of Action). Muscle relaxants given perioperatively with cholinesterase inhibitors may experience worsening of their disease in the presence of Persantine®.

Carboxigenesis, Mucocartilage, Impairment of Fertility In studies in which dipyridamole was administered in the feed and reduced the maximum daily oral dose to male rats (12.5 mg/kg daily, 1/4 times the maximum recommended daily oral dose) to males and females (12.5 mg/kg daily, 1/4 times the maximum recommended daily oral dose) to males and females (12.5 mg/kg daily, 1/4 times the maximum recommended daily oral dose) have revealed no evidence of impaired embryonic development due to dipyridamole. There are, however, no adequate and well controlled studies in pregnant women.

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 a study of 311 patients in whom intravenous Persantine® was used as an adjunct to thallium 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 node arrest, sinus node depression, conduction block, transient cerebral ischemia, asymptomatic cerebral lesions) that could lead to a false negative thallium imaging result (see Mechanism of Action).
CALL FOR ABSTRACTS FOR SCIENTIFIC PAPERS AND SCIENTIFIC EXHIBITS
the Society of Nuclear Medicine
44th Annual Meeting
June 1-6, 1997
San Antonio, Texas

The 1997 Scientific Program Committee, Scientific Exhibits Subcommittee and the Scientific & Teaching Sessions Committee solicit the submission of abstracts from members and nonmembers of the Society of Nuclear Medicine for the 44th Annual Meeting in San Antonio, TX. Accepted Scientific Paper and Scientific Exhibit abstracts will be published in a special supplement to the May issue of The Journal of Nuclear Medicine and accepted Technologist Section abstracts will be published in the June issue of the Journal of Nuclear Medicine Technology. Original contributions on a variety of topics related to nuclear medicine will be considered, including:
• Instrumentation and Data Analysis
• Radioassay
• Radiopharmaceutical Chemistry

Authors seeking publication for the full text of their papers are strongly encouraged to submit their work for immediate review to JNM, and for the technologist section, to JNMT.

The Scientific Paper and Exhibit abstract form can be obtained in the September and October 1996 JNM. You can also obtain an abstract form by writing to:
Society of Nuclear Medicine
Att: Abstracts
1850 Samuel Morse Drive
Reston, VA 20190
Tel: (703)708-9000
Fax: (703)708-9015
http://www.snm.org

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**DuPont Pharma Nuclear Cardiology Research Fellowship**

The Society of Nuclear Medicine (SNM) Awards Committee announces that a fellowship for $20,000 is available for July 1, 1997.

The objectives of this fellowship are to (1) Encourage physicians to enter the field of Nuclear Cardiology and (2) Support clinical research in any of the following areas: Gated SPECT, Heart Failure, CAD Prognosis or CAD in Women. Funds can be used to support the research and/or salary of the investigator. Preference will be given to those new to the field of Nuclear Cardiology. The Award will be announced at the next Annual SNM Meeting, June, 1997 in San Antonio, Texas.

*For more information and an application contact:*

THE SOCIETY OF NUCLEAR MEDICINE
SNM AWARDS COMMITTEE
1850 Samuel Morse Dr., Reston, VA 20190-5316
(703) 708-9000 / FAX: (703) 708-9015

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**MALLINCKRODT FELLOWSHIP**

Mallinckrodt, Inc. is announcing it’s Annual Fellowship of $30,000 for a physician fellow active in nuclear medicine research and/or development. The award is to further a research project involving the development of single photon radiopharmaceuticals or beta emitters to be used in nuclear medicine oncology. Applicants are asked to submit their curriculum vitae, a detailed account of their research project including prior accomplishments on the project, and future plans. Deadline for this year’s award is January 6, 1997. Requested information, along with at least two letters supporting the application, should be forwarded to: William J. MacIntyre, PhD, Society of Nuclear Medicine, 1850 Samuel Morse Drive, Reston, VA 20190. The recipient will be announced at the Annual Meeting of the Society of Nuclear Medicine.

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**DuPont Pharma Nuclear Oncology Research Fellowship**

The Society of Nuclear Medicine (SNM) Awards Committee announces that a fellowship for $10,000 is available for July 1, 1997.

The objectives of this fellowship are to (1) Encourage physicians to enter the field of Nuclear Oncology and (2) Support clinical research in the area of Technetium Tc 99m labeled compounds for breast imaging as a complement to mammography. Funds can be used to support the research and/or salary of the investigator. Preference will be given to those new to the field of Nuclear Oncology. The Award will be announced at the next Annual SNM Meeting, June, 1997 in San Antonio, Texas.

*For more information and an application contact:*

THE SOCIETY OF NUCLEAR MEDICINE
SNM AWARDS COMMITTEE
1850 Samuel Morse Dr., Reston, VA 20190-5316
(703) 708-9000 / FAX: (703) 708-9015
Palm Springs Riviera Resort and Racquet Club  
Monday, February 10, through Tuesday, February 11, 1997  

Call SNM Department: Meeting Services  
703-708-9000  

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DON'T FORGET THE MID-WINTER MEETING IS IN PALM SPRINGS, CALIFORNIA  

DATE: February 5-11, 1997  
LOCATION: The Palm Springs Riviera Resort and Racquet Club  
EDUCATION PROGRAM SPONSOR: The Computer and Instrumentation Council
Position Available
Brain SPECT Imaging Fellowship
A one or two year fellowship position in brain imaging is available beginning July 1, 1997 in the Division of Nuclear Medicine, Department of Radiology, at the University of Alabama Medical Center at Birmingham. Applicants should have completed a residency in nuclear medicine or radiology, have an intense interest in both clinical and research brain imaging and should be eligible for licensure in the state of Alabama. Successful candidates will assume a significant role in multiple research projects involving all aspects of clinical brain SPECT imaging, triple head dynamic brain SPECT, quantitative Xe-133 brain SPECT on the Picker Prism, and 4.1T NMR metabolic and MRS brain imaging. Please send letter of interest and curriculum vitae to: James M. Moantz, MD, PhD, Director of Neuro-Nuclear Imaging, Division of Nuclear Medicine, Department of Radiology, The University of Alabama at Birmingham, 619 South 19th Street, Birmingham, AL 35233-6835. Phone: 205-975-8336, Fax: 205-934-5589. E-mail: medy010@uabdpo.dpo.uab.edu (UAB is an Affirmative Action/Equal Opportunity Employer).

Fellowship
The Department of Radiology at the University of Pittsburgh School of Medicine is recruiting for a fellowship position in our PET Center Facility which has an active and growing clinical service and research effort in oncology, as well as a large neuroscience research program. This is a non-tenure stream position with an expected hiring date in the fall of 1996. The position requires a board eligible radiologist or nuclear medicine physician and preferably with ABNM or ABR certification. The physician should be licensed (or eligible for licensure) to practice medicine in the Commonwealth of Pennsylvania. Interested candidates should submit a curriculum vitae to: Carolyn Cislo Melzer, MD, Acting Medical Director, PET Facility, University of Pittsburgh Medical Center, Room B938, 200 Lothrop St., Pittsburgh, PA 15213. The University of Pittsburgh is an Affirmative Action, Equal Opportunity Employer.

Nuclear Medicine Physician
The Dept. of Radiological Sciences of the University of Oklahoma Health Sciences Center has an opening for a staff radiologist with specialization in nuclear medicine. Faculty rank and remuneration will depend on credentials and experience. Members of the nuclear medicine section provide coverage for the University Hospital (adult). Children’s Hospital of Oklahoma and the DVA Medical Center in Oklahoma City. The section is well-equipped and performs approximately 10,000 studies/yr in aggregate. The individual selected will have primary responsibilities in one of the adult units, but will be expected to provide cross coverage within the other units. In addition, the individual will spend at least one day a week covering other areas of radiology and will be included in radiology on-call coverage. If interested, please contact: Joe C. Leonard, MD, Chief, Pediatric Imaging Service, Children’s Hospital of Oklahoma, P.O. Box 26307, Oklahoma City, OK 73126.

Nuclear Medicine Residency
July 1997. Comprehensive imaging/RA/therapy program in 4 hospitals (private, county, VA) with 2500 total beds. Mobile imaging for over 200 ICU beds. Large pediatric population. Strong cardiovascular emphasis. State-of-the-art instrumentation including SPECT computer processing. Once year of ACGME-approved preparatory residency required prior to entry. Contact: Warren H. Moore, MD, Department of Radiology, Baylor College of Medicine, One Baylor Plaza, Houston, TX 77030. Baylor College of Medicine is an EO/AA employer.

PET Fellowship
Research fellowship in PET at the Northern California PET Imaging Center affiliated with the University of California at Davis, for one year starting 7/1/97. Active clinical and research facility, 800 studies per year in oncology, neurology and cardiology. BC/BE applicant expected to participate in interpretation of studies, oncologic PET research, presentation of results and teaching. Please send curriculum vitae to: Peter E. Valk, MD, Northern California PET Imaging Center, 3195 Folsom Blvd., Sacramento, CA 95816.

Postdoctoral Research Fellowship (MD, PhD): Cancer Imaging (UCSF and LBNL)
Two-year research fellowship in diagnostic oncology imaging. Research training focuses on NMR imaging and spectroscopy, as well as emission tomography (PET and SPECT). Equipment includes state-of-the-art MRI, PET and other imaging devices and laboratory facilities at the UCSF Department of Radiology and at the Lawrence Berkeley National Laboratory for Functional Imaging. Trainees work under direct guidance of a faculty preceptor. Program funded by the National Cancer Institute (T32 CA 66527). Minorities and women are encouraged to apply. Send inquiries to: Randall A. Hawkins, MD, PhD, Department of Radiology, University of California, San Francisco, (UCSF), 505 Parnassus Ave., San Francisco, CA 94143-0252. Phone: 415-476-1521. E-mail: randy_hawkins@radman1.ucsf.edu.

Radiopharmacist
Radiopharmacist position with the Henry M. Jackson Foundation at the Tomography Department (PETD) of the Clinical Center, National Institutes of Health, in Bethesda, MD. Active program in radiopharmaceuticals, radiopharmacy, imaging physics, and data analysis sciences. Resources include two medical cyclotrons, six hot cells and laboratories for radiochemistry, three PET tomographs (two brain units and a whole-body instrument) and computer hardware and software for the generation and analysis of physiological images. The radiopharmacist assists in total PETD quality assurance with primary responsibility for quality control of a wide variety of new and established PET radiopharmaceuticals. Applicants must possess a bachelor’s degree in pharmacy and be licensed to practice pharmacy. Applicants must also have experience in radiopharmacy (dispensing, sterility and apyrogenicity testing), and analytical techniques, e.g., HPLC, either through a formal training program or experience in a nuclear medicine department. Salary commensurate with qualifications. Excellent benefits package. Send a cover letter and resume to:

Human Resources Department Attn: PL1960489
Henry M. Jackson Foundation for the Advancement of Military Medicine 1401 Rockville Pike, Suite 600 Rockville, MD 20852 or E-mail at: hr@mail.hjf.org
AA/EOE

Position Wanted
ABNM certified, young physician with expertise in all clinical aspects of nuclear medicine seeks a temporary or permanent, part-time or full-time employment in a Veterans Administration Hospital. Please contact: Randy Hawkins, M.D., 313-493-3516.
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