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Kit for the preparation of Technetium Tc99m Sestamibi

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CARDIOLITE scans (SPECT) from a 62-year-old male with three prior myocardial infarctions (LFOV camera equipped with a high-resolution collimator, 64 x 64 matrix, 180° arc RAO to LPO, 64 projections, 25 s/projection)

Please see last page of advertisement for brief summary of prescribing information.

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Reference

Brief Summary

Cardiolite
Kit for the preparation of Technetium Tc99m Sestamibi

FOR DIAGNOSTIC USE

DESCRIPTION: Each 5 mL vial contains a sterile, non-pyrogenic, lyophilized mixture of:
Tetakis (2-methoxy isobutyl isonitrile) Copper (I) tetrafluoroborate - 1.0 mg
Sodium Citrate Dihydrate - 2.6 mg
L-Cysteine Hydrochloride Monohydrate - 1.0 mg
Mannitol - 20 mg
Stannous Chloride, Dihydrate, minimum (SnCl2+2H2O) - 0.025 mg
Stannous Chloride, Dihydrate, (SnCl2+2H2O) - 0.075 mg
Tin Chloride (Stannous and Stannic) Dihydrate, maximum (as SnCl2+2H2O) - 0.086 mg

Prior to lyophilization the pH is 5.3 to 5.9. The contents of the vial are lyophilized and stored under nitrogen.

This drug is administered by intravenous injection for diagnostic use after reconstitution with sterile, non-pyrogenic, oxidant-free Sodium Pertechnetate Tc99m Injection. The pH of the reconstituted product is 5.5 (5.0–6.0). No bacteriostatic preservative is present.

The precise structure of the technetium complex is Tc99m(MIBI)7+ whereas MIBI is 2-methoxy isobutyl isonitrile.

INDICATIONS AND USAGE: CARDIOLITE®, Kit for the preparation of Technetium Tc99m Sestamibi, is a myocardial perfusion agent that is used in distinguishing normal from abnormal myocardium, and in the localization of the abnormality, in patients with suspected myocardial infarction. It is also useful in the evaluation of myocardial function using the first-pass technique.

CONTRAINdications: None known.

WARNINGS: In studying patients in whom cardiac disease is known or suspected, take care to assure continuous monitoring and treatment in accordance with safe, accepted clinical procedure.

PRECAUTIONS:

GENERAL
The contents of the vial are intended only for use in the preparation of Technetium Tc99m Sestamibi and are not to be administered directly to the patient without first undergoing the preparative procedure (as outlined in the full prescribing information).

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.

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.

Radioisopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radioisotopes and whose experience and training have been approved by the appropriate government agency authorized to license the use of radioisotopes.

Carcinogenesis, Mutagenesis, Impairment of Fertility
In comparison with most other diagnostic technetium-labeled radioisopharmaceuticals, the radiation dose to the ovaries (1.5 rads/30 mCi) 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)BF4-, was evaluated for genotoxic potential in a battery of five tests. No genotoxic activity was observed in the Ames, CHO/HPTP and sister chromatid exchange tests (all in vitro). At cytotoxic concentrations (≥20 μg/ml), an increase in cells with chromatome aberrations was observed in the mouse lymphoma L5178Y assay. Cu(MIBI)BF4 did not show genotoxic effects in the in vivo mouse micronucleus test at a dose which caused systemic and bone marrow toxicity (9 mg/kg > 500 x maximal human dose).

Pregnancy Category C
Animal reproduction and teratogenicity studies have not been conducted with Technetium Tc99m Sestamibi. It is also not known whether Technetium Tc99m Sestamibi can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. There have been no studies in pregnant women. Technetium Tc99m Sestamibi should be given to a pregnant woman only if clearly needed.

Ideally, examinations using radioisopharmaceuticals, especially those elective in nature, of a woman of childbearing capacity, should be performed during the first few (approximately 10) days following the onset of menses.

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 metallic or bitter taste immediately after the injection of Technetium Tc99m Sestamibi. A few cases of transient headache, flushing and non-pruritic rash have also been attributed to administration of the agent. One patient demonstrated signs and symptoms consistent with seizure, 8 to 10 minutes after administration of the drug. No other adverse reactions specifically attributable to the use of Technetium Tc99m Sestamibi have been reported.

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

370 to 1110 MBq (10 to 30 mCi)
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 section in full prescribing information).

The patient dose should be measured by a suitable radioactivity calibration system imminently 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.

Table at room temperature (15 to 30°C) before and after reconstitution.

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

Table 4. Radiation Absorbed Doses from Tc99m Sestamibi

<table>
<thead>
<tr>
<th>Organ</th>
<th>2.0 hour void</th>
<th>4.8 hour void</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Rads/30 mCi</td>
<td>mGy/1110 MBq</td>
</tr>
<tr>
<td>Breasts</td>
<td>0.2</td>
<td>2.0</td>
</tr>
<tr>
<td>Gallbladder Wall</td>
<td>2.0</td>
<td>2.0</td>
</tr>
<tr>
<td>Small Intestine</td>
<td>3.0</td>
<td>3.0</td>
</tr>
<tr>
<td>Upper Large Intestine</td>
<td>5.4</td>
<td>55.5</td>
</tr>
<tr>
<td>Lower Large Intestine</td>
<td>3.9</td>
<td>40.0</td>
</tr>
<tr>
<td>Stomach</td>
<td>0.6</td>
<td>6.1</td>
</tr>
<tr>
<td>Heart Wall</td>
<td>0.5</td>
<td>5.1</td>
</tr>
<tr>
<td>Kidneys</td>
<td>2.0</td>
<td>20.0</td>
</tr>
<tr>
<td>Liver</td>
<td>0.6</td>
<td>5.8</td>
</tr>
<tr>
<td>Lungs</td>
<td>0.3</td>
<td>2.8</td>
</tr>
<tr>
<td>Bone Surfaces</td>
<td>0.7</td>
<td>6.8</td>
</tr>
<tr>
<td>Thyroid</td>
<td>0.7</td>
<td>7.0</td>
</tr>
<tr>
<td>Ovaries</td>
<td>1.5</td>
<td>15.5</td>
</tr>
<tr>
<td>Testes</td>
<td>0.3</td>
<td>3.4</td>
</tr>
<tr>
<td>Red Marrow</td>
<td>0.5</td>
<td>5.1</td>
</tr>
<tr>
<td>Urinary Bladder</td>
<td>2.0</td>
<td>20.0</td>
</tr>
<tr>
<td>Total Body</td>
<td>0.5</td>
<td>4.8</td>
</tr>
</tbody>
</table>


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

Prior to lyophilization the pH is between 5.3 and 5.9. The contents of the vials are lyophilized and stored under nitrogen. Store at room temperature (15 to 30°C) before and after reconstitution. Technetium Tc99m Sestamibi contains no preservatives.

Included in each of two (2) vial kit is one (1) package insert, five (5) vial shield labels and five (5) radiation warning labels. Included in each of five (5) vial kit is one (1) package insert, five (5) vial shield labels and five (5) radiation warning labels. Included in each of thirty (30) vial kit is one (1) package insert, thirty (30) vial shield labels and thirty (30) radiation warning labels.

The US Nuclear Regulatory Commission has approved this reagent kit for distribution to persons licensed to use byproduct material identified in 35.100 and 35.200 of 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 government agency.

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Please see the brief summary of prescribing information for CardioTec on the adjacent page.
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Kit for the Preparation of Technetium Tc 99m Teboroxime

FOR DIAGNOSTIC USE

DESCRIPTION
Each 5 mL reaction vial contains a sterile, nonpyrogenic, lyophilized formulation of 2.0 mg cyclohexanedione dioxidine, 2.0 mg methyl boronic acid, 2.0 mg pentetic acid, 9.0 mg citric acid, anhydrous; 100 mg sodium chloride, 50 mg gamma cyclodextrin and 0.058 mg (maximum) total tin expressed as stannous chloride (SnCl₂), 0.020 mg (minimum) stannous chloride (SnCl₂). The pH is adjusted with sodium hydroxide and/or hydrochloric acid prior to lyophilization. The contents of the vial are lyophilized and sealed under nitrogen at the time of manufacture. No bacteriostatic preservative is present.

When sterile, pyrogen-free sodium pertechnetate Tc 99m injection is added to the vial, and the solution is heated at 100°C for 15 minutes, the diagnostic agent Technetium Tc 99m Teboroxime is formed for administration by intravenous injection. The pH of the reconstituted product is 3.7 (range 3.3 to 4.1).

INDICATIONS AND USAGE
Technetium Tc 99m Teboroxime is a myocardial perfusion agent that is useful in distinguishing normal from abnormal myocardium in patients with suspected coronary artery disease using rest and stress techniques.

CONTRAINDICATIONS
None known.

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

PRECAUTIONS
General
Contents of the reaction vial are intended only for use in the preparation of Technetium Tc 99m Teboroxime and are not to be administered directly to the patient.

Contents of the kit before preparation are not radioactive. However, after the addition of sodium pertechnetate Tc 99m injection, adequate shielding of the final preparation must be maintained.

The components of the kit are supplied sterile and non-pyrogenic. Aseptic procedures normally employed in making additions and withdrawals from sterile, non-pyrogenic containers should be used during the addition of the pertechnetate solution and the withdrawal of doses for patient administration.

The technetium Tc 99m labeling reactions involved in preparing the agent depend on maintaining the stannous ion in the reduced state. Any oxidant present in the sodium pertechnetate Tc-99m supply may thus adversely affect the quality of the radiopharmaceutical. Hence, sodium pertechnetate Tc-99m containing oxidants should not be employed.

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.

As in the use of any radioactive material, care should be taken to minimize radiation exposure to the patient consistent with proper patient management and to ensure minimum radiation exposure to occupational workers.

Tc-99m Teboroxime should be formulated no more than 6 hours prior to clinical use.

Carcinogenesis, Mutagenesis, Impairment of Fertility
In comparison with most other diagnostic technetium labeled radiopharmaceuticals, the radiation dose to the ovaries (1.8 rads/50 mCi) is high. Minimal exposure (ALARA) is necessary in women of childbearing capability. (See Dosimetry subsection in DOSAGE and ADMINISTRATION section.)

No long-term animal studies have been performed to evaluate carcinogenic potential or to determine the effects of Cardiotec on fertility in males or females.

Three different mutagenicity assays (a reversion test with bacteria, a chromosomal aberration assay and an in vivo mouse micronucleus assay) conducted with cold (decayed) technetium labeled Cardiotec gave negative results.

Cardiotec was weakly positive for inducing forward mutations at the TK locus in L5178Y mouse lymphoma cells in the absence of metabolic activation (but only at high concentrations that were toxic to the cells and reduced growth to 33% or less relative to vehicle controls). Cardiotec was negative in this assay in the presence of metabolic activation.

Pregnancy Category C
Animal reproduction studies have not been conducted with Technetium Tc 99m Teboroxime. It is also not known whether Technetium Tc 99m Teboroxime can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Technetium Tc 99m Teboroxime should be given to a pregnant woman only if the expected benefits to be gained clearly outweigh the potential hazards.

Ideally, examinations using radiopharmaceuticals, especially those elective in nature, in women of childbearing capability, should be performed during the first few (approximately 10) days following the onset of menses.

Nursing Mothers
Technetium Tc 99m is excreted in human milk during lactation. 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
Uncommon adverse reactions reported in clinical trials include metallic taste in mouth, burning at injection site, facial swelling, numbness of hand and arm, hypotension and nausea after administration of Technetium Tc 99m Teboroxime.

HOW SUPPLIED
Cardiotec* (Kit for the Preparation of Technetium Tc 99m Teboroxime) is supplied in kits of 5, 10, and 25 reaction vials.

(14-282A)

Reference
1. Data on file, Squibb Diagnostics.
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The Midwestern Chapter--SNM/TS will provide a referral network for technologists seeking employment and for hospitals in need of technologists. Interested individuals should call Cathy Gonzalez at (301) 855-1712. Please leave your name, address, phone number and a brief description of your request.

NOTE: SNM chapters are invited to submit job referral service listings for publication. Pertinent information—name and brief description of the service, telephone number and/or address, name or number of contact person for inquiries—should be sent to:

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Microscope Objectives

Optics for Research offers a new product line of long working distance objectives designed for laser trimming, circuit shaping, and semiconductor probing. There are three types of Microspot focusing objectives, all with the universal RMS thread. There are 12 different models, including both all-refractive and all-reflective objectives, from 5x to 60x. Specific models are available with NAs as high as 0.65. The objectives include models for the UV excimer and the YAG lasers. Optics for Research, Inc., Box 82, Caldwell, NJ 07006. (201) 228-4480.

Circle Reader Service No. 101

Video Memory Storage

Colorado Video, Incorporated has introduced the 493-4 Video Peak Store, a video memory instrument. The unit allows an operator to make a series of four separate time exposures, ranging from a few seconds each to several hours each. The video output of each of the four 512 x 480 x 8 bit memories may be viewed separately on individual TV monitors or connected to a RGB monitor for creation of a synthesized color image. Any of the four memories may be operated as a simple frame grabber as well as in the time exposure mode. An "exposed" image may also be reversed in video polarity to create a negative picture. The addition of a simple video mixer allows the operator to subtract one image from the other to show only differences. The 493-4 may be used as a stand-alone instrument or connected to a computer through an optional I/O package. Applications include tracing the path of radio-opaque dye, capture of random events, gait analysis, tracking of moving subjects, electro-optical scan conversion, and displacement measurements.

Glen Southworth, Colorado Video, Incorporated, P.O. Box 928, Boulder, Colorado 80306. (303) 530-9580.

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Network System

Canberra Nuclear announces the addition of the X-Genie Network system to its Genie products family. The X-Genie system combines the X-Windows user interface and X-Terminal Display with Canberra's complete library of analysis software to provide an extremely flexible system for data collection, real time spectral display and analysis for gamma spectroscopy, alpha spectroscopy, neutron activation analysis, and whole-body counting applications. The X-Genie provides workstation style graphics in a multi-user system. The standard X-Windows user interface allows the operator to view multiple windows at one time, each running different applications. Multichannel Analyzer (MCA) windows allow the operator to control data-collection devices and to view spectra and associated parameters. Therefore, experiments can be controlled, applications executed, or data reviewed from any X-Terminal connected to the system. Application programs such as the ABACOS-PLUS whole-body counting package can interact with MCA windows to facilitate calibration, operator feedback, and ease of use, providing an optimum user-interface environment.

Marl Davidson, Canberra Nuclear Data Systems, 150 South Spring Lake Drive, Itasca, IL 60143. (708) 285-3000.

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Deluxe Ultrasound Table

Atomic Products Corporation introduces the Deluxe Ultrasound Table, which combines Trendelenburg and Fowler back positioning with various table adjustments. The table has three main positions (horizontal, chair, and Trendelenburg), and will lock in the chosen position. A simple foot-operated hydraulic jack allows rapid height adjustment of the table top for easy loading and unloading of the patient. The table may be raised or lowered to the proper scanning height once the patient is comfortably positioned. The unit can be tilted into the Trendelenburg position with up to a 15° angle by using the crank handle. The back can be positioned at five separate angled increments. The leg support has two positions, vertical or horizontal, and will lock into place. The table top consists of a two-inch thick, foam-rubber pad covered with heavy Naugahyde to ensure patient comfort. Two adjustable velcro straps are included for patient stability. Atomic Products Corporation, P.O. Box 702, Shirley, NY 11967. (516) 924-9000.

Circle Reader Service No. 105

Compact Gamma Counter

Bioscan, Inc. has added QC-Gamma™ to its Quick-Count™ family of low-cost, compact counters. QC-Gamma is a sophisticated, single-well gamma counter, offering performance equivalent to automated and multiwell counters at less than half the price. It uses only one square foot of bench space and features a built-in data processor and graphics printer, high counting efficiency (greater than 75% for 123I), and dual-isotope counting for 123I and 57Co. Speed, accuracy, convenient benchtop access, and flexibility make the QC-Gamma ideal for research work. In RIA labs, it increases productivity and throughput by counting and analyzing low-volume assays without interrupting high-volume counting. Real-time assay results are generated by 11 pre-programmed RIA data reduction methods including logit-log, point-to-point linear and log, and two-point IRMA. Data can also be exported for further analysis or archiving by other computers via RS-232C output. Continuous optimum performance is ensured by automatic high-voltage adjustment and detector calibration plus pre-programmed quality assurance routines. MIA Gross, Bioscan, Inc., 4590 MacArthur Blvd., NW, Washington, DC 20007. (202) 338-0974.

Circle Reader Service No. 108

Calibrator Irradiator

J.L. Shepherd & Associates have introduced the Mini Model 1425S, a completely self-contained panoramic calibrator, designed to irradiate large numbers of TLDs, film badges, or pocket dosimeters of any manufacturer. The maximum delivered dose variation is ±2%, typically ±1%, with less than 3% scatter component. Five dosimeter racks are provided. The low external radiation level, small size, light weight, and mobility permit this device to be used in virtually any laboratory location. An optional single attenuator with a value of up to X-10 provides an additional lower dose rate to dosimeters. The control panel of the Mini 1425S contains all operational function pushbuttons, switches, and indicator lights for the device. Once the turntable switch is activated and the source on button is pressed, the source cannot be raised and the dosimeters irradiated unless the turntable is rotating. The source remains exposed until the preset time expires. Travel time is less than 0.5 second in either direction. The source is immediately returned to the fully shielded “off” position whenever the preset time expires; the “off” switch, which overrides the timer, is pressed; electrical power is turned off; or air pressure is lost. J.L. Shepherd & Associates, 1010 Arroyo Avenue, San Fernando, CA 91340. (818) 898-2361.

Circle Reader Service No. 106

Ultrasound System

Acuson Corporation has introduced a new premium performance black and white ultrasound system, the Acuson® 128XP/3 Computed Sonography System. The new system takes advantage of the highly configurable technology of Acuson’s new 128XP platform and sets a new price performance standard for black and white, high performance diagnostic ultrasound. All models of the XP™ platform, including the XP/3 are based on Acuson computed sonography, a fundamentally different approach to imaging, which utilizes a 128-channel, software-optimized system to produce images that are significantly higher in quality than those made by previous available technology. One capability of the new system is 128-channel curved array imaging that utilizes the powerful image formation of the Acuson XP platform and new transducer technology. This technology overcomes the far-field degradation and imaging artifacts common with conventional curved linear transducers. The XP/3 can be field upgraded to Acuson’s more fully configured premium performance color Doppler radiology and cardiovascular ultrasound systems. William Courtney, Acuson Corporation, 1220 Charleston Road, P.O. Box 7393, Mountain View, CA 94039. (415) 969-9112.

Circle Reader Service No. 107

38A
This year Nuclear Medicine Week will be observed from July 28–August 3. Nuclear Medicine Week, sponsored by The Society of Nuclear Medicine and Technologist Section, was developed to educate the general public and health care professionals of the diagnostic and treatment capabilities of nuclear medicine.

Nuclear Medicine Week is the only time during the year that the entire nuclear medicine community unites to present its message. It is an excellent opportunity to reach out to those who could benefit from nuclear medicine; it is also a most opportune time to promote your facility to referring physicians and potential patients.

A new poster, button and sticker have been designed to help you promote this worldwide event in your community. In addition, a set of guidelines with suggestions to increase participation is available from the Society. We encourage all those involved in nuclear medicine to join with us to increase the awareness and improve the perception of nuclear medicine.

To purchase posters, buttons and stickers for your institution, and to receive a guidelines packet, visit the Nuclear Medicine Week booth located in the registration area of the Convention Center.
CELEBRATE
NUCLEAR MEDICINE WEEK
July 28 – August 3, 1991

The following materials are available for promoting Nuclear Medicine Week in your area.

One poster, sticker, and a button, all in full color, have been designed for this year.

Posters — $5.00 each, 4 – 9 posters are $4.50 each, 10 or more $4.00 each.
I would like _______ posters × $ _______ $ __________

Buttons — $1.00 each
I would like to order _______ buttons $ __________

Stickers — $.25 each (same design as the button)
I would like to receive _______ stickers.
(Minimum order is 10 stickers) $ __________
Total $ __________

☐ I would like to order a free set of Guidelines for promoting Nuclear Medicine Week.

Payment must be enclosed with your order. Payments must be made in U.S. dollars drawn on U.S. banks. No foreign funds will be accepted. Make checks payable to The Society of Nuclear Medicine

Orders will be sent out by 1st class mail or UPS. Orders received after July 1, 1991 will be assessed a 15% surcharge, payable before shipment, to ensure timely delivery.

Please return this form to:
Nuclear Medicine Week
The Society of Nuclear Medicine
136 Madison Avenue,
New York, NY 10016-6760
We’ve removed your PET collar

PET perfusion studies without a cyclotron

CardioGen-82® (Rubidium Rb 82 Generator) is the only generator-based myocardial perfusion agent indicated for PET imaging.

Now in 45 to 60 minutes you can have PET images to help you distinguish normal from abnormal myocardium. All without the expense of a cyclotron!

The short 75-second half-life lowers the radiation burden to the patient. When incorporated into the Rubidium Infusion System, serial imaging of myocardial blood flow changes can be performed as often as every ten minutes.

The CardioGen-82 System also improves patient throughput and scheduling efficiency by enabling you to perform multiple studies in a short time.

Remove the PET collar from your department. Get the PET images you need in 45 to 60 minutes, without a costly cyclotron.

CardioGen-82®
Rubidium Rb-82 Generator

Please see adjacent page for brief summary of prescribing information.
SPECT BRAIN IMAGING
CLINICAL FELLOWSHIP

Department of Radiology
Section of Nuclear Medicine

BENEFITS:
This program is designed for nuclear medicine physicians, radiologists, technologists and referring physicians. It is intended to educate participants about the clinical utility of SPECT brain imaging with agents such as SPECIamine® and Ceretec®. Objectives include:

- Development of interpretation skills for brain images.
- Appreciation of clinical applications of SPECT brain imaging.
- Knowledge of image acquisition and reconstruction.
- Appreciation of factors that influence image quality.
- Knowledge of quality control techniques for SPECT.

SPONSORSHIP:
This program is sponsored by the Medical College of Wisconsin.

TUITION:
The tuition fee of $650 includes the course syllabus, handouts, breaks, breakfasts, lunches, and other amenities involved in making this a pleasant learning experience. Maximum enrollments have been established. Cancellations prior to the course will be refunded, less a $30 administrative fee.

CREDIT:
The Medical College of Wisconsin is accredited by the Accreditation Council for Continuing Medical Education to sponsor continuing medical education for physicians.

Accordingly, the Medical College of Wisconsin designates this continuing medical education activity as meeting the criteria for 13.00 hours in Category I toward the Physician’s Recognition Award of the American Medical Association.

Nuclear Medicine Technologists who attend the SPECT Brain Imaging Clinical Fellowship are eligible for 1.0 VOICE credit.

Register me for the following dates: (Please indicate a second choice)


I will need hotel reservations for: 

☐ Sunday and Monday night/only Monday night.

I will need a ______ single/_______ double room.

A check in the amount of $650 should accompany this registration form and be made payable to the Medical College of Wisconsin. Telephone registrations must be confirmed by check within 10 days.

Name

Address

City/State/Zip

Office Phone (_____) _______ work address

Home Phone (_____) _______ home address

Registrations and payment should be sent to:
Lisa Ann Trembath
SPECT Brain Imaging Fellowship Coordinator
Nuclear Medicine Division
Medical College of Wisconsin
8700 W. Wisconsin Avenue
Milwaukee, WI 53226 (414) 257-6068

CardioGen-82® Rubidium Rb 82 Generator

INDICATIONS AND USAGE
Rubidium chloride Rb 82 injection is a myocardial perfusion agent that is useful in distinguishing normal from abnormal myocardium in patients with suspected myocardial infarction.

Cardiogen-82 (Rubidium Rb 82 Generator) must be used with an infusion system specifically labeled for use with the generator and capable of accurate measurements and delivery of doses of rubidium chloride Rb 82 injection not exceeding a single dose of 2220 MBq (60 mCi) and a cumulative dose of 4440 MBq (120 mCi) at a rate of 50 MBq/min with a maximum volume per infusion of 100 mL and a cumulative volume not to exceed 300 mL. These performance characteristics reflect the conditions of use under which the drug development clinical trials were conducted.

Adequate data from clinical trials to determine the role of localization of myocardial infarction or identification of stress-induced ischemia have not been collected.

Positron emission tomographic (PET) instrumentation is recommended for use with rubidium chloride Rb 82 injection.

CONTRAINDICATIONS
None known.

WARNINGS
Caution should be used during infusion as patients with congestive heart failure may experience a transitory increase in circulatory volume load. These patients should be observed for several hours following the Rb-82 procedure to detect delayed hemodynamic disturbances.

PRECAUTIONS
General
Data are not available concerning the effect of marked alterations in blood glucose, insulin, or pH (such as is found in diabetes mellitus) on the quality of rubidium chloride Rb 82 scans. Attention is directed to the fact that rubidium is physiologically similar to potassium, and since the transport of potassium is affected by these factors, the possibility exists that rubidium may likewise be affected.

Rubidium chloride Rb 82 injection must be administered only with an appropriate infusion system capable of meeting the performance characteristics previously described. (See INDICATIONS AND USAGE.) The drug should be used only by those possessing a thorough understanding of the use and performance of the infusion system.

Repeat doses of rubidium chloride Rb 82 injection may lead to an accumulation of the longer lived radioactive contaminants strontium Sr 82 and strontium Sr 86. Since eluate obtained from the generator is intended for intravenous administration, aseptic techniques must be strictly observed in all handling. Only additive free Sodium Chloride Injection USP should be used to elute the generator. Do not administer eluate from the generator if there is any evidence of foreign matter.

As in the use of any radioactive material, care should be taken to minimize radiation exposure to the patient consistent with proper patient management and to insure minimum radiation exposure to occupational workers. 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.

Carcinogenesis, Mutagenesis, Impairment of Fertility
No long-term studies have been performed to evaluate carcinogenic potential, mutagenicity potential, or to determine whether rubidium Rb 82 may affect fertility in males or females.

Pregnancy Category C
Animal reproductive studies have not been conducted with rubidium Rb 82. It is also not known whether rubidium Rb 82 can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Rubidium Rb 82 should be given to pregnant women only if the expected benefits to be gained clearly outweigh the potential hazards.

Ideally, examinations using radiopharmaceuticals, especially those examinations which are elective in nature, in women of childbearing capability should be performed during the first few (approximately 10) days following the onset of menarche.

Nursing Mothers
It is not known whether rubidium Rb 82 is excreted in human milk. Due to the short half-life of rubidium Rb 82 (78 sec) it is unlikely that the drug would be excreted in human milk during lactation. However, because many drugs are excreted in human milk, caution should be exercised when rubidium Rb 82 is administered to nursing women.

Pediatric Use
Safety and effectiveness in children have not been established.

ADVERSE REACTIONS
No adverse reactions specifically attributable to rubidium Rb 82 have been reported during controlled clinical trials.

HOW SUPPLIED
Cardiogen-82 (Rubidium Rb 82 Generator) is supplied in the form of strontium Sr 82 adsorbed on a hydroxyapatite column with an activity of 90-150 milliequivalents Sr-82 at calibration time. The generator is encased in a lead shield surrounded by a labeled plastic container. Complete assay data for each generator are provided on the container. Cardiogen-82 (Rubidium Rb 82 Generator) is intended for use only with an appropriate, properly calibrated infusion system labeled for use with the generator.

issued: March 1991

Circle Reader Service No. 77
High Performance Scintigraphy—
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Current Studies
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- High Resolution Imaging of other Anatomies
- Thyroid Uptake
- Bone Densitometry
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Spatial Resolution:
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- Medium Energy Isotopes (I-131): 5 mm

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Cardiotec®

Kit for the Preparation of Technetium Tc 99m Teboroxime

FOR DIAGNOSTIC USE

DESCRIPTION

Each 5 mL reaction vial contains a sterile, non-pyrogenic, lyophilized formulation of 2.0 mg cyclohexanedione dioxime, 2.0 mg methyl boronic acid, 2.0 mg pentetic acid, 9.0 mg citric acid, anhydrous; 100 mg sodium chloride, 50 mg gamma cyclodextrin and 0.058 mg (maximum) total tin expressed as stannous chloride (SnCl₂). 0.020 mg (minimum) stannous chloride (SnCl₂). The pH is adjusted with sodium hydroxide and/or hydrochloric acid prior to lyophilization. The contents of the vial are lyophilized and sealed under nitrogen at the time of manufacture. No bacteriostatic preservative is present. When sterile, pyrogen-free sodium pertechnetate Tc 99m injection is added to the vial, and the solution is heated at 100°C for 15 minutes, the diagnostic agent Technetium Tc 99m Teboroxime is formed for administration by intravenous injection. The pH of the reconstituted product is 3.7 (range 3.3 to 4.1).

INDICATIONS AND USAGE

Technetium Tc 99m Teboroxime is a myocardial perfusion agent that is useful in distinguishing normal from abnormal myocardium in patients with suspected coronary artery disease using rest and stress techniques.

CONTRAINDICATIONS

None known.

WARNINGS

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

PRECAUTIONS

General

Contents of the reaction vial are intended only for use in the preparation of Technetium Tc 99m Teboroxime and are not to be administered directly to the patient.

Contents of the kit before preparation are not radioactive. However, after the addition of sodium pertechnetate Tc 99m injection, adequate shielding of the final preparation must be maintained. The components of the kit are supplied sterile and non-pyrogenic. Aseptic procedures normally employed in making additions and withdrawals from sterile, non-pyrogenic containers should be used during the addition of the pertechnetate solution and the withdrawal of doses for patient administration. The technetium Tc 99m labeling reactions involved in preparing the agent depend on maintaining the stannous ion in the reduced state. Any oxidant present in the sodium pertechnetate Tc-99m supply may thus adversely affect the quality of the radiopharmaceutical. Hence, sodium pertechnetate Tc-99m containing oxidants should not be employed.

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.

As in the use of any radioactive material, care should be taken to minimize radiation exposure to the patient consistent with proper patient management and to ensure minimum radiation exposure to occupational workers. Tc-99m Teboroxime should be formulated no more than 6 hours prior to clinical use.

Carcinogenesis, Mutagenesis, Impairment of Fertility

In comparison with most other diagnostic technetium labeled radiopharmaceuticals, the radiation dose to the ovaries (1.8 rads/50 mCi) is high. Minimal exposure (ALARA) is necessary in women of childbearing capability. (See Dosimetry subsection in DOSAGE and ADMINISTRATION section.)

No long-term animal studies have been performed to evaluate carcinogenic potential or to determine the effects of Cardiotec on fertility in males or females. Three different mutagenicity assays (a reversion test with bacteria, a chromosomal aberration assay and an in vivo mouse micronucleus assay) conducted with cold (decayed) technetium labeled Cardiotec gave negative results. Cardiotec was weakly positive for inducing forward mutations at the TK locus in L5178Y mouse lymphoma cells in the absence of metabolic activation (but only at high concentrations that were toxic to the cells and reduced growth to 33% or less relative to vehicle controls). Cardiotec was negative in this assay in the presence of metabolic activation.

Pregnancy Category C

Animal reproduction studies have not been conducted with Technetium Tc 99m Teboroxime. It is also not known whether Technetium Tc 99m Teboroxime can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Technetium Tc 99m Teboroxime should be given to a pregnant woman only if the expected benefits to be gained clearly outweigh the potential hazards.

Ideally, examinations using radiopharmaceuticals, especially those elective in nature, in women of childbearing capability, should be performed during the first few (approximately 10) days following the onset of menses.

Nursing Mothers

Technetium Tc 99m is excreted in human milk during lactation. 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

Uncommon adverse reactions reported in clinical trials include metallic taste in mouth, burning at injection site, facial swelling, numbness of hand and arm, hypotension and nausea after administration of Technetium Tc 99m Teboroxime.

HOW SUPPLIED

Cardiotec® (Kit for the Preparation of Technetium Tc 99m Teboroxime) is supplied in kits of 5, 10, and 25 reaction vials. (J4-282A)

Reference

1. Data on file, Squibb Diagnostics.

550-503
550-503

Issued: March 1991
**NEW!**

CardioTec®

(Kit for the Preparation of Technetium Tc-99m Tetroxime)

THE ONLY TECHNETIUM-BASED AGENT FOR STRESS AND REST

**QUICK...**
Rapid uptake and washout: complete stress and rest studies in only 90 minutes!

**CLEAR...**
Sharp images: enhance diagnostic ability to distinguish ischemia and infarction!

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Rapid blood clearance: greater patient comfort.

The first technetium-based myocardial perfusion agent for rest and stress imaging.

NEW CardioTec®

(Kit for the Preparation of Technetium Tc-99m Tetroxime)

*SQUIBB Diagnostics*

Please see the brief summary of prescribing information for CardioTec on the adjacent page.