Extended expiration—Expiration time is increased to 12 hours after time of calibration.

Better patient dosimetry—Improved radionuclidic purity reduces patient radiation exposure.
Superior image quality—
Reduced interference from radionuclidic impurities enhances image quality over an extended shelf-life.

Phantom studies comparing SPECTamine® (Iofetamine HCI I 123 Injection) labeled with Te 124 (p,2n) iodine I 127 (p,5n) iodine

For additional information on the use of SPECTamine®, contact your local Medi-Physics Territory Manager, MPI Professional Service Center or call 1-800-451-7732.

Your partner in advancing nuclear medicine

For complete product information, consult package insert, a brief summary of which follows:

DIAGNOSTIC – FOR INTRAVENOUS USE
DESCRIPTION: SPECTamine® Iofetamine HCI I 123 Injection, is supplied as a sterile, apyrogenic, aqueous, iodotabeled sodium chloride solution for intravenous administration. Each milliliter of the solution contains 37 megabequers (1 millicurie) of Iofetamine HCI I 123 at calibration time, 0.15 milligram Iofetamine HCI, 0.017 millimole sodium phosphate, and 8.0 milligrams sodium chloride for isotonicity. The pH is adjusted to 4.5-6.0 with sodium hydroxide or hydrochloric acid. SPECTamine contains no bacteriostatic preservative and is packaged in single dose vials. The radionuclidian composition at calibration time is not less than 98.6 percent I 123, not more than 1.9 percent I 125, and not more than 0.1 percent all others (I 126 and I 127). The radionuclidian composition at the 12-hour expiration time is not less than 96.3 percent I 123, not more than 3.5 percent I 125, and not more than 0.2 percent all others.

INDICATIONS AND USAGE: SPECTamine (Iofetamine HCI I 123 Injection) is recommended for use as a lipophilic brain-imaging agent. It has been shown to be useful in the evaluation of noncancerous lesions especially when used within 20 hours of onset of local neurological deficit. The rates of agreement between abnormal images and the neurological examination suggestive of ischemic cerebrovascular insufficiency appear to increase with the severity of symptoms. Its usefulness for the measurement of cerebral blood flow has not been established.

CONTRAINDICATIONS: None known.

WARNINGS: SPECTamine (Iofetamine HCI I 123 Injection) should not be administered to individuals with known hypersensitivity to SPECTamine and/or to those individuals taking monoamine oxidase inhibitors.

PRECAUTIONS: General
Some patients (Macaca fascicularis) studies have shown marked eye uptake of Iofetamine HCI I 123. Localization has not been studied in the isolated human eye although in vivo images suggest the concentration of Iofetamine HCI I 123 is below the limit of detection. Individual human variations in pharmacokinetics of the drug and the long-term effects on the eye have not been evaluated. The contents of the vial are radioactive. Adequate shielding of the preparation must be maintained at all times. Do not use after the expiration time and date (12 hours after calibration time) stated on the label. Potassium Iodide Oral Solution should be administered before the examination to minimize thyroid uptake of Iofetamine I 123.

The prescribed Iofetamine HCI I 123 dose should be administered as soon as possible from the time of receipt of the product (i.e., as close to calibration time or before, if possible), in order to minimize the fraction of radiation exposure due to relative increase of radionuclidian contaminants with time. To minimize radiation dose to the blader, the patient should be encouraged to drink fluids and void frequently. SPECTamine, as well as other radioactive drugs, must be handled with care. Appropriate safety measures should be used to minimize radiation exposure to clinical personnel. Care should also be taken to minimize radiation exposure to the patient consistent with proper patient management.

Radioactive materials should be used 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.

Drug Interactions
There has been a single report of elevated diastolic hypertension (about 30 mm Hg) occurring 18 hours after administration of SPECTamine in a patient maintained on therapeutic doses of vaspatic acid.

Concurrent use of monoamine oxidase (MAO) inhibitors and compounds containing the amphetamine structure has been known to result in hypertensive crisis. Caution, therefore, should be exercised when administering SPECTamine (Iofetamine HCI I 123 Injection) to individuals taking medications known to potentiate the effects of sympathomimetic amines. It is recommended that SPECTamine not be administered during or within 14 days following administration of MAO inhibitors.

Sympathomimetic amines may affect the biodistribution of SPECTamine and, thus, may influence the image quality and diagnostic utility of the image.

Category of Fertility
Cardiovascular, Metabolic, Impairment of Fertility
No long-term animal studies have been performed to evaluate carcinogenic potential, mutagenic potential or effects on fertility in male or female animals. The Ames test was negative for mutagenic effects.

Pregnancy Category C
Animal reproduction studies have not been conducted with SPECTamine. It is also not known whether SPECTamine can cause fetal harm when administered to a man or a pregnant woman or can affect reproduction capacity. SPECTamine should be given to a pregnant woman only if clearly needed.

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

Meningoceles
Since iodine I 123 is excreted in human milk, formula feeding should be substituted for breast feeding if the agent must be administered to the mother during lactation.

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

ADVERSE REACTIONS: In a clinical study in 93 patients with sudden onset of focal neurologica1 deficit, e.g., cerebral infarction; 7 patients died within 2 to 5 days after administration. The deaths were considered to be a result of the disease state. Although there was no concurrent control group, statistics from historical controls support this evaluation. There is evidence suggesting that the administration of 1 to 2 milligrams of iodotabeled HCl, the carrier in SPECTamine, may increase systolic blood pressure by about 10 mm Hg. In a patient with a history of hypertension, there has been a single report of sudden onset of hypertension and dizziness with transient chest tightness which occurred 5-10 minutes after administration of SPECTamine. One case of transient unilateral hearing loss also was reported several hours after the use of SPECTamine in a patient with a coincidental upper respiratory infection. As with all organic-iodine-containing compounds, the possibility of allergic reactions must be considered.

HOW SUPPLIED: SPECTamine is supplied in nominal 3.5 ml vials as a sterile, apyrogenic, aqueous, iodotabeled sodium chloride solution for intravenous injection. Each milliliter contains 37 megabequers (1 mCi) of Iofetamine HCI I 123 at calibration time. It is available in individual vials containing 111 megabequers (3 mCi) of Iofetamine HCI I 123 at calibration time in a volume of 3 ml. Single use vials are packaged in individual lead shields with plastic outer container.
NRC REQUIREMENT:
“A licensee shall survey for removable contamination, once each week, all areas where radiopharmaceuticals are routinely prepared for use, administered or stored.”

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Detector technology has reached full maturity—beyond this point it's unreasonable to expect significant advances.

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The new sophycamera DSX uses the same digital detector technology as the DS7, and delivers the same outstanding accuracy and consistency. But the DSX also features a large 21.2" x 15.75" rectangular UFROV, 94 PMTs. Making it the premier system for whole-body and SPECT studies.

Together, the DS7 and DSX comprise the sophycamera family. Their unparalleled digital accuracy will change your sense of what's possible in detector technology.
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What that means for you is a real improvement in data accuracy and consistency. You can depend on the DS7 to give you better diagnostic information, day after day.

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In 1984, sopha medical introduced 32-bit computing to nuclear medicine. We knew the effect on clinical performance—and on our own growth—would be revolutionary.
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A 32-bit processor, by itself, is not magical. For our sophycamera and sophy computer systems, we've developed a comprehensive 32-bit computing architecture. It provides one 32-bit chip for imaging, another for acquisition. Full scale 32-bit parallel data buses. Ample high-speed memory. And an open format for ready dialogue with the outside world. But even that's not magical.

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The Amersham Ceretec™ kit is supplied as packs of 5 single dose vials each in the preparation of a technetium Tc99m exametazime intravenous injection as a diagnostic radiopharmaceutical for use as an adjunct in the detection of altered regional cerebral perfusion in stroke.

INDICATIONS AND USAGE
Technetium Tc99m exametazime scintigraphy may be useful as an adjunct in the detection of altered regional cerebral perfusion in stroke.

CONTRAINDICATIONS
None known.

PRECAUTIONS
The contents of the Ceretec vial are not radioactive. However, after the sodium pertechnetate Tc99m is added, adequate shielding of the vial and any required handling must be maintained.

A thorough knowledge of the normal distribution of intravenously administered technetium Tc99m exametazime injection is essential in order to interpret studies accurately.

This technetium Tc99m labeling reaction involves in preparing technetium Tc99m exametazime injection depends on maintaining tin (IV) in the presence of excess sulfuric acid. The tin (IV) is reduced by the tin (II) in the beta emitting technetium that results from isotope separation in vacuum. As shown in Table 2, for a vial, a use of 2.7 mm thickness, more radiation exposure is a factor of 1,000.

To correct for physical decay of this radionuclide, the fraction of remaining activity intervals relative to the time of calibration are shown in Table 3.

<table>
<thead>
<tr>
<th>Shield thickness (mm)</th>
<th>Coefficient of attenuation</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.2</td>
<td>0.20</td>
</tr>
<tr>
<td>0.95</td>
<td>0.05</td>
</tr>
<tr>
<td>1.8</td>
<td>0.012</td>
</tr>
<tr>
<td>2.1</td>
<td>0.002</td>
</tr>
<tr>
<td>4.5</td>
<td>0.0005</td>
</tr>
</tbody>
</table>

To correct for physical decay of this radionuclide, the fraction of remaining activity intervals relative to the time of calibration are shown in Table 3.

<table>
<thead>
<tr>
<th>Physical decay chart — Tc99m half-life 6.03 hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hours</td>
</tr>
<tr>
<td>-------</td>
</tr>
<tr>
<td>0</td>
</tr>
<tr>
<td>2.5</td>
</tr>
<tr>
<td>5</td>
</tr>
<tr>
<td>7.5</td>
</tr>
<tr>
<td>10</td>
</tr>
<tr>
<td>12.5</td>
</tr>
<tr>
<td>15</td>
</tr>
<tr>
<td>17.5</td>
</tr>
<tr>
<td>20</td>
</tr>
</tbody>
</table>

Table 4. Estimated absorbed radiation dose

<table>
<thead>
<tr>
<th>Target organ</th>
<th>Absorbed radiation dose Tc99m exametazime injection (cGy/MBq)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Larynx</td>
<td>0.035</td>
</tr>
<tr>
<td>Gallbladder wall</td>
<td>0.021</td>
</tr>
<tr>
<td>Kidney</td>
<td>0.013</td>
</tr>
<tr>
<td>Mucosa</td>
<td>0.007</td>
</tr>
<tr>
<td>Bladder</td>
<td>0.005</td>
</tr>
<tr>
<td>Rectal lumen</td>
<td>0.007</td>
</tr>
<tr>
<td>Small intestine</td>
<td>0.007</td>
</tr>
<tr>
<td>Large intestine</td>
<td>0.006</td>
</tr>
</tbody>
</table>

Caution: Federal (U.S.A.) Law prohibits dispensing without a prescription.

Prior to publication of the USAN, exametazime was formerly known as hexamethylpropylene amine oxime (HMPAO). The name HMPAO appears in many publications.

When sterile pyrogen-free sodium pertechnetate Tc99m in isotonic saline is added to the vial, a Tc99m complex of exametazime is formed.

Administration is by intravenous injection for diagnostic use.

Physical Characteristics
Technetium Tc99m is produced by isomeric transition with a physical half-life of 6.03 hours. Physiologic conditions that are useful for imaging studies are listed in Table 4.

Table 1. Principal radiation emission data — technetium Tc99m

<table>
<thead>
<tr>
<th>Gamma energy (keV)</th>
<th>Decay time (h)</th>
</tr>
</thead>
<tbody>
<tr>
<td>140.5</td>
<td>87.87</td>
</tr>
</tbody>
</table>


Other valuable data concerning the properties of the Tc99m labelled exametazime complex are shown in Table 4.

Table 4. Estimated absorbed radiation dose

<table>
<thead>
<tr>
<th>Target organ</th>
<th>Absorbed radiation dose Tc99m exametazime injection (cGy/MBq)</th>
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<td>Small intestine</td>
<td>0.007</td>
</tr>
<tr>
<td>Large intestine</td>
<td>0.006</td>
</tr>
</tbody>
</table>

*Data supplied by Oak Ridge Associated Universities, Radiopharmaceutical Internal Dose Information Center.

ANIMAL TOXICOLOGY
Accidental intravenous injections have been performed on intravenously administered technetium Tc99m in male and female rats and rabbits. No adverse reactions or mortality were observed at a dose equivelent to the single injection of 1200 times the maximum human equivalent dose. Fourteen day repeat-dose studies in rats and rabbits at a cumulative dose of up to 14,000 times the maximum human equivalent dose did not reveal adverse reactions, abnormal pathology, or mortality. At necropsy, thorough histopathologic, hematology and blood chemistry revealed no abnormalities.

HOW SUPPLIED
The kit comprises the five individual vials of sterile, non-ysogenic, freeze-dried mixture of exametazime stannous chloride diphosphate sodium chloride, for injection, for oral use, alcohol swabs, five radiopharmaceutical purity worksheets, and one package insert. The vial and contents are sealed under a nitrogen atmosphere with a rubber stopper.

PROCEDURE
For the Preparation of Technetium Tc99m Exametazime Injection

Use aseptic technique throughout.

1) Place one of the vials in a suitable shielding container and aseptically open the rubber septum of the sterile swab provided.

2) Using a 10 ml syringe, inject into the shielded vial of sterile eluate from a technetium Tc99m generator (see notes 1-4). Before withdrawing the syringe from the vial withdraw 5 ml of gas from the space above the solution to normalize the pressure in the vial. Shake the shielded vial for 10 seconds to ensure complete dissolution of the powder.

3) Assay the total activity and calculate the volume to be injected. The eluate should be made up to a suitable radiouclide calibration system immediately prior to administration.

4) Complete the label provided and attach to the shielded vial. The technetium Tc99m exametazime injection is ready for quality control.

5) Maintain adequate shielding of the radiopharmaceutical.

6) Do not use the preparation more than 3 minutes after time of formulation. Discard any unused material.

7) Visually inspect the injection site and surrounding area for evidence of local irritation or discoloration and report to qualified health personnel.

Cautionary Notes

1. 0.37-1.11 GBq (10-30 mCi) technetium Tc99m may be added to the vial.

2. Before constitution the generator eluate may be adjusted to the correct radiotracer concentration (0.37-1.11 GBq [10-30 mCi]).

3. The generator eluate should be used for injection immediately in a suitable radiouclide calibration system immediately prior to administration.

4. Complete the label provided and attach to the shielded vial. The technetium Tc99m exametazime injection is ready for quality control.

5) Maintain adequate shielding of the radiopharmaceutical.

6. Do not use the preparation more than 3 minutes after time of formulation. Discard any unused material.

7. Visually inspect the injection site and surrounding area for evidence of local irritation or discoloration and report to qualified health personnel.

The Illinois Department of Nuclear Safety has approved this reagent kit for distribution to persons licensed for use by product material identified in §25.200 of 10 Part 30-39. All personnel to persons who hold an equivalent license issued by an Agreement State.

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USP Drug Product Problem Reporting Program
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# Radiopharmaceutical Identification

1. Name of radiopharmaceutical prepared agent
   
   Manufacturer's name and address
   
   Central pharmacy name and address (if applicable)
   
   Radioactivity concentration
   
   Assay date and time
   
   Preparation time
   
   Calibration date
   
   Expiration date

2a. Tc-99m generator
   
   □ Check here if not applicable
   
   Brand name
   
   Size
   
   Ci
   
   Lot #
   
   Calibration date and time
   
   Date and time of current and last elution
   
   ;
   
   Exp. date
   
   Amount and volume Tc-99m added to kit or given to patient
   
   Manufacturer's name and address
   
   Central pharmacy name and address (if applicable)

2b. Kit
   
   □ Check here if not applicable
   
   Name of kit
   
   Lot #
   
   Volume diluted to
   
   Expiration date
   
   Kit heated
   
   □ No
   
   □ Yes
   
   duration
   
   Manufacturer's name and address
   
   Central pharmacy name and address (if applicable)

2c. Were manufacturer drug preparation methods strictly adhered to?
   
   □ Yes
   
   □ No
   
   □ Not applicable

2d. If non-radioactive drugs were used in association with radiopharmaceuticals, please list here
   
   ____________________________________________________________

# Product Administered to Patient

3. Problem noted or suspected
   
   □ Adverse reaction
   
   □ Other
   
   □ Altered biodistribution

4. Describe the problem (Please give time sequence of events, attach additional pages if necessary.)

4a. Was interpretation of image possible?
   
   □ Yes
   
   □ No
   
   □ Not applicable

5. Patient information
   
   a. Patient initials
   
   b. Suspected disease
   
   c. Concurrent drugs, doses and frequency
   
   d. Other disease states

6. Administration information
   
   Activity administered
   
   mCi (Circle one)
   
   Volume administered
   
   mL
   
   Route of administration
   
   Date and time of administration (indicate AM or PM)
   
   Site of administration
   
   Other patients received dose from same lot
   
   □ Yes
   
   □ No
   
   Did they experience any reaction or altered biodistribution?
   
   □ Yes
   
   □ No
   
   If yes, please file a report for each reaction
   
   Number of patients
7. Adverse reaction information

<table>
<thead>
<tr>
<th>Date and time of reaction onset</th>
<th>Your interpretation of reaction cause</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Recovered, no treatment necessary</td>
<td>[ ] Allergic</td>
</tr>
<tr>
<td>[ ] Died (date ___)</td>
<td>[ ] Pyrogenic</td>
</tr>
<tr>
<td>[ ] Alive, with sequelae</td>
<td>[ ] Pharmacologic effect</td>
</tr>
<tr>
<td>[ ] Recovered, required treatment</td>
<td>[ ] How classified (briefly)</td>
</tr>
<tr>
<td>[ ] due to product</td>
<td>[ ] unknown</td>
</tr>
<tr>
<td>[ ] due to other cause</td>
<td>[ ] Compounding error</td>
</tr>
</tbody>
</table>

8. Problem noted or suspected (check all that apply)

| [ ] Product identification incorrect | [ ] Packaging compromised |
| [ ] Radiochemical impurity | [ ] Radionuclide impurity |
| [ ] pH high | [ ] pH low |
| [ ] Other ____________________ | [ ] Color/clarity/foreign matter |
| [ ] Particle size/number | [ ] Heating period too long or short |

9. Describe the problem


10. Test(s) if any (include ITLC data, particle size, etc.), performed to confirm problem


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IIb. Name and address of institution

IIc. Phone number, please indicate times you are available at workplace.

12. Please indicate to whom USP may voluntarily disclose your identity (check boxes that apply).

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13. If requested, is sample of involved product available for examination?

| [ ] Yes | [ ] No | [ ] Sent to manufacturer |

14. Signature and date

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Proceedings of the Midwinter Meeting of the
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Well illustrated, this 16-page pamphlet explains what nuclear medicine is, how the procedures are performed, and how they can help in the early detection of disease.

Divided into 3 sections, the guide opens with a general overview of nuclear medicine. A question-and-answer section follows, addressing such topics as safety, the benefits of nuclear medicine procedures, pre- and post-instructions, and testing of pregnant women and children. The third section explains some of the more commonly performed procedures such as bone, liver, lung, heart, and thyroid uptake scans.

16 pp; 5½ × 8½; in 2 colors;
25¢ per pamphlet; minimum order: 100 copies

Guidelines for Patients Receiving Radioiodine Treatment

Prepared in collaboration with the U.S. Nuclear Regulatory Commission, this 8-page pamphlet answers patients’ questions about home care after receiving radioiodine treatment for thyroid conditions.

Easy-to-read language outlines important precautions patients can follow to help reduce radiation exposure to others. It also contains a checklist that physicians can review with their patients to determine which guidelines are appropriate for them and how they should be followed.

8 pp; 5½ × 8½; in 2 colors;
30¢ per pamphlet; minimum order: 25 copies

Healthcare professionals in private practice, hospitals, and clinics will find that these pamphlets provide a brief, attractive, and inexpensive way to educate patients and their families about the importance and safety of nuclear medicine procedures.

TO ORDER: Single copies are available for review at $1.50 each. All prices include postage and handling. Prepayment required in U.S. funds drawn on U.S. banks only. Make checks payable to: The Society of Nuclear Medicine. Prices are in U.S. dollars and subject to change without notice.

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Nuclear Medicine: Self-Study Program I is the successor to the highly acclaimed Nuclear Medicine Review Syllabus, which reviewed the major advances in nuclear medicine in the 1970's. Nuclear Medicine Review Syllabus, under the editorship of Peter Kirchner, MD, sold 4,000 copies, more than any other SNM title for nuclear medicine physicians.

NUCLEAR MEDICINE: SELF-STUDY PROGRAM I
Edited by Barry A. Siegel, MD, and Peter T. Kirchner, MD

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If you are a physician, scientist or technologist who needs to review his knowledge of nuclear medicine, or one who wants to know more about this cutting edge of medicine, order your copy today.
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To provide up-to-date information about the most accurate procedures for ensuring quality control of radiopharmaceuticals, The Society of Nuclear Medicine has published *Chromatography of Technetium-99m Radiopharmaceuticals—A Practical Guide*.

This important manual offers readers a collection of miniaturized chromatographic methods for the rapid and precise determination of the radiochemical purity of commonly used Tc-99m radiopharmaceuticals. Topics covered include the nature and source of impurities, principles and classic techniques of chromatography, methods for counting miniature chromatographic strips, and pitfalls of miniature methods and how to avoid them. Also contained herein is a listing of each radiopharmaceutical with the USP criteria for radiochemical purity, typical scans of impure products, and standards and interlaboratory comparisons for miniaturized systems.

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EUROPEAN ASSOCIATION
OF NUCLEAR MEDICINE
CONGRESS 1989

AUGUST 28 – SEPTEMBER 1
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SCIENTIFIC PROGRAM

Plenary sessions, with lectures given by invited speakers, will feature the following main topics: Oncology, Emission Tomography, Cardiology, Pediatrics, Neurology. Scientific Papers, Works-in-Progress, Technicians' Program, Scientific and Commercial Exhibition, and Pre- and Post-Congress Meetings are also included.

Topics related to nuclear medicine will be considered for inclusion in the scientific program as follows:

Clinical science applications: Cardiology and Circulation, Bone/Joint Diseases, Pulmonary Diseases, Neurology, Nephrology, Hematology, Endocrinology, Pediatrics, Gastroenterology, Oncology, Immunology, Infectious Diseases

Physical science—basic research: Computers and Data Analysis, NMR: Imaging and In Vivo Spectroscopy, Dosimetry, Radiobiology, Instrumentation

Laboratory science and in vitro applications: Radioassay, Tumor Markers, Cell Labeling, Genetic Engineering

Radio pharmaceutical: General, Halogens, Positrons, Proteins/Antibodies, Technetium

EXHIBITION

A comprehensive exhibition of equipment and radio pharmaceutical manufacturers will be on display.

Registration and fees:

Non-Members of European Association of Nuclear Medicine:

By June 15 the registration fee for non-members will be 1425 FF, VAT included. After June 15 the registration fee for non-members will be 1780 FF, VAT included.

Members of European Association of Nuclear Medicine: If EANM member fees are registered by April 1: no Congress fee. If EANM member fees are registered after April 1: full Congress fee must be paid minus 120 DM (membership fee), i.e.:

—925 FF, VAT included, by June 15, 1989
—1280 FF, VAT included, after June 15, 1989

Social Program

A comprehensive social program has been planned, including the Opening Ceremony with a concert and welcome cocktail (free of charge), a concert in the Cathedral of Strasbourg, a folklore evening in the Alsatian vineyard (Riquewhir), a dinner dance in the Pourtales Castle near Strasbourg, and the Farewell Party in the Orangerie Gardens.

Accompanying persons' program: Numerous and attractive excursions and activities are planned.

PRESIDENT OF THE CONGRESS: Prof. Jacques Chambron

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Faculté de Médecine
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New Products

Each description of the products below was condensed from information supplied by the manufacturer. The reviews are published as a service to the professionals working in the field of nuclear medicine and their inclusion herein does not in any way imply an endorsement by the Editorial Board of The Journal of Nuclear Medicine or by The Society of Nuclear Medicine.

New SPECT-Align
Gammex, Inc., has introduced SPECT-Align, a new three-laser patient alignment system for SPECT to facilitate data acquisition. Quality of diagnostic information and efficiency are significantly improved. SPECT-Align is so accurate that the images produced can be superimposed. Because of this accuracy, subtle changes can be detected and quantified analysis is possible. Cut-off problems and untrue reconstruction planes are eliminated. Direct comparison of transmission CT and SPECT-IMP studies are now possible. The versatile SPECT-Align works well with any SPECT system, all room layouts, and individual procedure needs. Request Bulletin No. 28 for full information. Gammex, Inc., 9722 W. Watertown Plank Road, PO Box 26708, Milwaukee, WI 53226. (414)258-7188.

Vyleater Disposal System
A five-minute narrated videotape describes the features and applications of the Vyleater disposal system for small glass and plastic containers, including scintillation vials. The Vyleater automatically empties and crushes vials and other small containers, separating liquids and solids in the process. Liquids are drained off to a secure container for appropriate waste treatment. Crushed containers are collected in a 55 gallon drum. By greatly reducing the bulk of waste to be disposed of and retrieving as much as 95% of the liquid once held by the containers, the Vyleater has saved thousands of dollars for the many industrial, medical, and research laboratories using the machine. To obtain a copy of the video without charge, contact: S&G Enterprises, Inc., 8626 N. 91st St., Milwaukee, WI 53225. (1(800) 233-3721.

Cardiac Software Package
ADAC Laboratories has announced a works-in-progress high speed automatic cardiac software package for use with the ADAC DPS 33000 and DPS 33000 Micro nuclear medicine computer systems. This new automated cardiac package generates several cardiac parameters such as Fourier analysis, ejection fraction, ejection indices, and volume curve analysis. The package calculates ejection fraction utilizing edge-following areas of interest with a program that automatically draws the frame by frame AOIs and subtracts background. The search algorithm is based on a Laplacian filter method. Fourier analysis is applied to cyclic cardiac images to create functional images yielding information about heart chamber activity, which is difficult to obtain by visual inspection of the images. Fourier analysis images provide information about regional variation in blood volume change and chambers or parts of chambers contracting out of synchrony. The ejection indices and volume curve analysis computes and displays ejection index parameters relating to emptying and filling of the left ventricle. Results include a derivative of the original volume curve and an ejection indices report. Final display creates a composite of Fourier images, end diastole/end systole images, ejection fraction, and volume curve. This new package will eventually feature batch processing capabilities, allowing multiple patient and/or views to be processed without operator intervention. ADAC Laboratories, 540 Alder Dr., Milpitas, CA 95035. Attn. Bruce C. Quill. (415)863-2413.

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For complete prescribing information consult package insert. A brief summary of which follows:

DIAGNOSTIC — FOR INTRAVENOUS USE

DESCRIPTION: The kit consists of 10 multidose reaction vials which contain the sterile, non-pyrogenic, non-radioactive ingredients necessary to produce Technetium Tc 99m Albumin Aggregated Injection for diagnostic use by intravenous injection.

Each 10 ml reaction vial contains 2.5 mg of Albumin Aggregated. 5.0 mg of Albumin Human, 0.08 mg (minimum) stannous chloride (maximun stannous and stannic chloride: 0.11 mg and 1.2 mg of sodium chloride; the contents are in a lyophilized form under an atmosphere of nitrogen. Sodium hydroxide or hydrochloric acid has been used for pH adjustment. No bacteriostatic preservative is present.

The Albumin Human was non-reactive when tested for hepatitis B surface antigen (HbsAg) by radioimmunoassay. The aggregated albumin is formed by denaturation of the Albumin Human in a heating and aggregation process. Each vial contains 4 to 6 million particles. Light microscopy, each containing aggregating factors present.

INDICATIONS AND USAGE: Technetium Tc 99m Albumin Aggregated Injection is a labeling agent which may be used as an adjunct in the evaluation of pulmonary perfusion in adults and children.

CONTRAINDICATIONS: Technetium Tc 99m Albumin Aggregated Injection should not be administered to patients with severe pulmonary hypertension. The use of Technetium Tc 99m Albumin Aggregated Injection is contraindicated in persons with a history of hypersensitivity reactions to products containing human serum albumin.

WARNINGS: Although adverse reactions specifically attributable to Technetium Tc 99m Albumin Aggregated Injection have not been noted, the literature contains reports of deaths occurring after the administration of Albumin Aggregated to patients with pre-existing severe pulmonary hypertension. Hypersensitivity reactions and anaphylactic reactions to components of Technetium Tc 99m Albumin Aggregated Injection have been reported.

PRECAUTIONS:

General:
The contents of the kit before preparation are not radioactive. However, after the sodium pertechnetate to Tc 99m is added, adequate shielding of the final preparation must be maintained.

In patients with right to left heart shunts, additional risk may exist due to the rapid entry of Albumin Aggregated into the systemic circulation. The safety of this agent in such patients has not been established.

Hypersensitivity reactions are possible whenever protein-containing materials such as Albumin Aggregated are used in man. Epinephrine, antihistamines, and corticosteroids should be available for immediate use.

The intravenous administration of any particulate materials such as Albumin Aggregated imparts a temporary small mechanical impediment to blood flow. While this effect is probably physiologically insignificant in most patients, the administration of Albumin Aggregated is possibly hazardous in acute or pulmonary disease and other states of severely impaired pulmonary blood flow.

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.

Contents of the vials are intended only for use in the preparation of Technetium Tc 99m Albumin Aggregated Injection and are NOT to be administered directly to the patient.

The Technetium Tc 99m labeling reactions involved depend on maintaining the stannous ion in the reduced state. Hence, sodium pertechnetate to Tc 99m containing oxidants should not be employed.

The preparation contains no bacteriostatic preservative. Technetium Tc 99m Albumin Aggregated Injection should be stored at 2-8°C and discarded 6 hours after reconstitution.

Technetium Tc 99m Albumin Aggregated Injection is physically unstable and consequently the particle size with time. Failure to agitate the vial adequately before use may result in non-uniform distribution of radioactive particles. If blood is drawn into the syringe, unnecessary delay prior to injection may result in clot formation in site.

Do not use if clumping of the contents is observed.

Technetium Tc 99m Albumin Aggregated, as well as other radioactive drugs must be handled with care. Once sodium pertechnetate to Tc 99m is added to the vial, appropriate safety measures must be used to minimize radiation exposure to clinical personnel. Care must also be taken to minimize the radiation exposure to patients in a manner 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 radionuclides and whose experience and training have been approved by the appropriate government agency. Careful use of radionuclides will follow the principles of the safe use of radionuclides.

Cardiogenic, Mediopathy of Fertility

No long term animal studies have been performed to evaluate carcinogenic potential or whether Technetium Tc 99m Albumin Aggregated Injection affects fertility in males or females.

Pregnancy Category C

Animal reproduction and teratogetic studies have not been conducted with Technetium Tc 99m Albumin Aggregated Injection. It is not known whether Technetium Tc 99m Albumin Aggregated Injection can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. There have been no studies in pregnant women. Technetium Tc 99m Albumin Aggregated Injection should be given to a pregnant woman only if clearly needed.

Identifying examinations using radiopharmaceuticals, especially those selective 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 Tc 99m is excreted in human milk during lactation. Therefore, formula feedings should be substituted for breast feedings.

Pediatric Use

The lowest possible number of particles should be used in right-to-left shunting, in neonates, and in severe pulmonary disease.

ADVERSE REACTIONS:

The literature contains reports of deaths occurring after the administration of Albumin Aggregated to patients with pre-existing severe pulmonary hypertension. Instances of hemodynamic or dysrhythmic reactions to preparations of Technetium Tc 99m Albumin Aggregated have been reported (see Warnings).

HOW SUPPLIED:

MPI MAA Kit

Kit for the Preparation of Technetium Tc 99m Albumin Aggregated Injection

Product No. 4432

Each kit contains 10 reaction vials. Each vial containing lyophilized form, sterile and non-pyrogenic:

- Albumin Aggregated
- Albumin Human
- Stannous Chloride (minimum)
- Sodium Chloride

For use in the preparation of Technetium Tc 99m Albumin Aggregated Injection.

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