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Phantom studies comparing SPECTamine® (lofetamine HCl I 123 Injection) labeled with
Te 124 (p,2n) iodine 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® (lofetamine HCl I 123 Injection) is supplied as a sterile, aqeous, isotonic sodium chloride solution for intravenous administration. Each milliliter of the solution contains 37 megabequerels (1 millicurie) of iodetamine HCl I 123 at calibration time, 0.15 milligram iodetamine HCl, 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 radionuclidic composition at calibration time is not less than 98.0 percent I 123, not more than 0.1 percent I 125 and I 127, and not more than 0.1 percent I 127 and Te 121. The radionuclidic 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 (lofetamine HCl I 123 Injection) is recommended for use as a liquid-soluble brain-imaging agent. It has been shown to be useful in the evaluation of nonorganic stroke especially when used within 96 hours of onset of local neurological deficit. The rates of agreement between abnormal images and the neurological examination supportive 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 (lofetamine HCl I 123 injection) should not be administered to individuals with known hypersensitivity to sympathomimetic amines or to those individuals taking monoamine oxidase inhibitors.

PRECAUTIONS: General

Some primates (Macaca fascicularis) have shown marked eye uptake of iodetamine HCl I 123. Localization has not been studied in the isolated eye although in vivo images suggest the concentration of iodetamine HCl I 123 is below the limit of detection. Individual human variations in pharmacokinetics of this drug and the long-term effect 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 iodine 123. The prescribed Iodetamine HCl I 123 dose should be administered as soon as practical 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 radionuclidic contaminants with time.

To minimize radiation dose to the bladder, 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.

Radiopharmacists 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.

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 valproic acid.

Concurrent use of monoamine oxidase (MAO) inhibitors and compounds containing the amphetamine structure has been shown to result in hypertensive crisis. Caution, therefore, should be exercised when administering SPECTamine (lofetamine HCl 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.

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

Cardiogenic, Myocardial, 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 if it will 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 childbearing capability, should be performed during the first few (approximately ten) days following the onset of menses.

Nursing Mothers

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 neurological deficit, e.g., cerebral infarction, 7 patients died within 2 to 55 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 I 123 to 2 milligrams of iodetamine HCl, the content 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-solvent-containing compounds, the possibility of allergic reactions must be considered.

HOW SUPPLIED: SPECTamine is supplied in nominal 3.5 ml vials as a sterile, aqeous, isotonic sodium chloride solution for intravenous injection. Each milliliter contains 37 megabequerels (1 millicurie) of iodetamine HCl I 123 at calibration time. It is available in individual vials containing 11 megabequerels (3 millicurie) of iodetamine HCl I 123 at calibration time.

It is available in individual vials containing 11 megabequerels (3 millicurie) of iodetamine HCl I 123 at calibration time in a volume of 3 ml. Single use vials are packaged in individual lead shields with plastic outer container.

THIS PRODUCT INFORMATION ISSUED AUGUST 1988

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Please see following page for full prescribing information.
Ceretec™ for the preparation of Technetium Tc99m Exametazime Injection

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 final preparation must be maintained.

The contents of the Ceretec™ vial are intended only for use in preparation of the exametazime injection and are NOT to be administered directly to the patient.

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

The technetium Tc99m labeling reaction in preparing technetium Tc99m exametazime injection depends on maintaining tin (IV) in the dosing solution. The oxidant present in the sodium pertechnetate Tc99m employed may adversely affect the quality of the technetium Tc99m containing oxidants should not be used for the preparation of the labeled product. A technetium generator must be eluted within 24 hours prior to obtaining any eluate for reconstitution with the Ceretec kit.

Sodium Chloride Injection, USP must be used as the diluent. Do not use bacteriostatic sodium chloride as a diluent for sodium pertechnetate Tc99m injection because it will increase the oxidation products and adversely affect the biological distribution of Ceretec.

GENERAL
The contents of the Ceretec™ vial are sterile and pyrogen free. The vial contains no bacteriostatic preservative. It is essential that the user follow the manufacturer's instructions and adhere to strict aseptic procedures for preparation of the radiopharmaceutical.

Technetium Tc99m exametazime injection, like other radiopharmaceuticals, is not appropriate for use in patients who are allergic to starch or other appropriate 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.

Radiopharmaceuticals should be used only by or under the control of physicians who are qualified by training and experience in the safe use and handling of radionuclides and whose experience and training has been approved by the appropriate governmental agency authorized to license the use of radionuclides.

To minimize radiation dose to the bladder, the patient should be encouraged to void when the examination is completed and as often thereafter as is comfortable. Adequate hydration should be encouraged to permit frequent voiding.

Carogenesis, Nuitrogenesis, Impairment of Fertility

Long-term animal studies have been performed to evaluate carcinogenic potential of technetium Tc99m exametazime in female and male animals. Studies in rats did not demonstrate statistically significant increases in histopathological abnormalities.

Nursing Mothers

Technetium Tc99m exametazime is excreted in human milk during lactation. It is not known whether this radiopharmaceutical is excreted in human milk. Therefore, formula feedings should be substituted for breast feeding.

ADVERSE REACTIONS
Rash with generalized pruritus, facial edema, and fever has been reported. A transient increase in blood pressure was seen in 8% of patients.

DOSAGE AND ADMINISTRATION

The user should wear waterproof gloves and use shielding at all times when handling the vial and syringes.

The recommended dose range for intracerebral examination with technetium Tc99m exametazime is 70-370 MBq (2-10 mCi).

Do not use the final radiopharmaceutical preparation more than 30 minutes after time of reconstitution. Discard any unused material.

Dynamic imaging may be performed between 0 to 10 minutes following injection. If the examination is prolonged, the patient may be performed from 15 minutes up to 6 hours after injection.

Although gross abnormalities of regional cerebral perfusion may be visualized by planer imaging techniques, it is recommended that SPECT imaging be carried out to maximize the value of the study.

RADIATION DOSIMETRY

Based on the patient's absorbed radiation dose to an average human adult (70 kg) from an intravenous injection of this product is estimated to be 0.026 mSv (0.026 rad) and 0.044 mSv (0.044 rad) with simultaneous scalp exposure.

*Data supplied by Oak Ridge Associated Universities, Radioisotope Safety Information Center.

ANIMAL TOXICOLOGY SUMMARY

Acute toxicity studies have been performed on intravenously administered Ceretec in male and female rats and rabbits. No adverse reactions or testicular atrophy were observed at a dose equivalent 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 dose equivalent did not show any adverse reactions, abnormalities, or mortality. At termination, thorough histopathology, hematologic and blood chemistry revealed no abnormalities.

HOW SUPPLIED

The kit contains five individual vials of sterile, non-pyrogenic, freeze-dried mixture of exametazime sodium chloride-di- hydrogen phosphate, 14 mg stannous chloride, five sterile alcohol swabs, five radiographic purity worksheets, and one patient information insert. The vial and contents are sealed under a nitrogen atmosphere with a rubber stopper.

PROCEDURE

For the Preparation of the Technetium Tc99m Exametazime Injection

Use aseptic technique throughout.

1. Place one of the vials in a suitable shielding container and remove the rubber stopper with the rubber stopper provider.

2. Using a 10 ml syringe, inject into the shielded vial 5 ml of sterile saline from a technetium Tc99m generator (see notes 1) before withdrawing the vial from saline with 5 ml of saline 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. Add the total activity and calculate the volume to be injected. The patient dose should be measured in a suitable radiobiological activity system immediately prior to administration.

4. Complete the label provided and attach to the vial shield. The technetium Tc99m was prepared for administration without any equivalent material.

5. Visually inspect the reconstituted material at a safe distance behind leaded glass, and do not use if there is evidence of foreign material.

CAUTIONARY NOTES

1. 0.37-1.11 GBq (10-30 mCi) technetium Tc99m may be used and will not cause radioactivity in the environment.

2. Before reconstitution the generator eluate may be adjusted to provide the correct radioactive concentration with 0.37-1.11 GBq (10-30 mCi) in 5 ml of saline with preservative-free non-bacteriostatic saline for injection.

3. Generator eluate more than 2 hours old should not be used.

For the highest radiobiological purity reconstitute with sterile normal saline from a technetium Tc99m generator eluate.

4. Use only eluate from a technetium Tc99m generator which was prepared within the last 2 hours.

5. The pH of the prepared injection is in the range 9.0-9.8.

Storage

Store shielded shielded at 2-8°C. Store the formulated drug at room temperature (15-25°C) using appropriate radiobiochemistry.

The Illinois Department of Nuclear Safety has approved this reagent lot and has granted a distribution to persons licensed to use product material identified in 25,200 of SCR Part 35 and refuses to hold an equivalent license issued by an Agreement State.

Manufactured by: Amersham International plc

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Fundamentals of Nuclear Medicine

2nd Edition

Edited by
Naomi P. Alazraki, MD
and
Fred S. Mishkin, MD

Completely Revised and Updated

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CONGRESS 1989
AUGUST 28 – SEPTEMBER 1
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Physical science—basic research:
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Call for Abstracts for Works-in-Progress
The 1989 Scientific Program Committee solicits the submission of abstracts from members and nonmembers of The Society of Nuclear Medicine for the 36th Annual Meeting in St. Louis. Works-in-Progress accepted for the program will be published in a separate on-site show directory that will be distributed to all those who attend the meeting. Original contributions on a variety of topics related to nuclear medicine will be considered, including:

- INSTRUMENTATION
- COMPUTERS AND DATA ANALYSIS
- RADIOASSAY
- RADIOPHARMACEUTICAL CHEMISTRY
- DOSIMETRY/RADIOBIOLOGY
- NUCLEAR MAGNETIC RESONANCE
- CLINICAL SCIENCE APPLICATIONS
  - Bone/Joint
  - Cardiovascular
  - Endocrine
  - Gastroenterology
  - Infectious Disease
  - Neurology
  - Oncology/Hematology
  - Pediatrics
  - Pulmonary
  - Renal/Hypertension
  - Immunology

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

A complete educational program for technologists will be offered and technologists are encouraged to submit abstracts of their work for consideration.

The official abstract form for Works-in-Progress may be obtained from the September 1988 issue of the JNM or by calling or writing:

The Society of Nuclear Medicine
Attn: Abstracts
136 Madison Avenue, New York, NY 10016-6760
Tel: (212) 889-0717
FAX: (212) 545-0221

Deadline for Works-in-Progress is Thursday, April 7, 1989
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 Video Imager

Packard Instrument Company has introduced its Cobra™ One single detector gamma-counting system. With advanced technology based on multichannel analysis and built-in computer control, this basic low-cost CPM system provides cost-effective upgrading capabilities through hardware and software modules. The system is easily configured to meet today’s laboratory applications, and its modularity and expandability make it suited for future applications without investing in new equipment. The Cobra One system offers a choice of either a two-inch or three-inch NaI(Tl) detector. Three counting regions, a 15 to 2000 keV energy range, and low background allow precise counting of both high and low energy radionuclides.

MZ-Display Software

ADAC Laboratories has announced that its newest nuclear medicine dynamic software release will incorporate a new multi-zone display program named MZ-Display. This new program allows the user greater flexibility in the presentation and formatting of multiple image sets from the same patient or from several different patients. The program is designed for use with the ADAC DPS 33000 and DPS 3300 Micro computer systems. MZ-Display makes extensive use of the mouse for menu selections and produces multiple display zones that contain graphics as well as images. The program automatically sets up the number of zones to be displayed depending on the number of image sets (called screen groups) that are selected, or the number of zones can be selected from the menu. For SPECT thallium users, both stress and redistribution images in four, six, eight, or 16 zones can be displayed. The program will separate the two image sets into groups that can be operated together or separately. The groups can be realigned and displayed in either forward or reverse cine and can be normalized, scaled, or enhanced to provide optimum screens. This new program, which requires the use of the ADAC array processor for its operations, allows ADAC users to control the display of data as never before. ADAC Laboratories, 540 Adler Dr., Milpitas, CA 95035. Attn: Bruce Quill. (408) 945-2990.

The unit can provide unattended sample processing due to its 1000-tube capacity sample changer and 60 user programs. Volume independence is achieved through the use of protocol-adjustable elevator positions, which align the sample in the optimum location for counting, regardless of sample volume. A powerful built-in IBM-compatible computer features a 20Mb hard drive and a 3.5-inch floppy disc drive to accept and run a variety of software products and operate all system functions. Packard Instrument Company, 2200 Warrenville Rd., Downers Grove, IL 60515. Attn: Jim Vondran. (312) 969-6000.

Circle Reader Service No. 102

Matrix Instruments, Inc., has announced the introduction of its Color Compact Video Imager—the first compact film recorder capable of recording multiple color images on a single sheet of 8-inch or 10-inch film. Only 9.5" high by 15.5" wide by 28.5" deep, the color compact can be ordered in versions that will generate four or six images, in color or black and white, on standard or instant print sheet film or transparencies. At the heart of this recorder is the Matrix RGB filter wheel assembly, with which color components are sequentially displayed on a high resolution monochrome CRT, resulting in a superior quality color composite of the superimposed red, green, and blue exposures. This capability makes this imager ideal for color flow doppler ultrasound, nuclear medicine, and other color applications. To maximize reliability, the Color Compact Video Imager uses microprocessor electronics that have been proven in many other Matrix recorders. Built-in software ensures simple initial calibration and set-up for consistent, optimal performance. In addition, memories store up to four sets of image parameters for recall at any time. Matrix Instruments, Inc., 1 Ramland Rd., Orangeburg, NY 10962. Attn: Susan Hubener. (914) 365-0190.

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* Lyophilized product offers excellent stability
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* Up to 100 mCi per reaction vial
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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 lyophilized 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 Tc, 0.06 mg (minimum) stannous chloride (maximum 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 was non-reactive when tested for hepatitis B surface antigen (HBsAg) by radioimmunoassay. The aggregated particles are formed by denaturation of Albumin Human in a heating and aggregation process. Each vial contains 4 to 6 million particles. By light microscopy, more than 98% of the particles are between 10 and 70 micrometers, while the typical average size is 20 to 40 micrometers; none is greater than 150 micrometers. Technetium Tc 99m Albumin Aggregated Injection for intravenous use is in its final dosage form when sterile isotonic sodium pertechnetate solution is added to each vial. No less than 99.9% of the pertechnetate Tc 99m added to a reaction vial is bound to aggregate at preparation time and remains bound throughout the 6-hour lifetime of the preparation.

**INDICATIONS AND USAGE:** Technetium Tc 99m Albumin Aggregated Injection is a long imaging 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 hyperfunction.

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 have not been noted, the literature contains reports of deaths occurring after the administration of Albumin Aggregated to patients with pre-existing serious pulmonary hyperfunction. Instances of hemolytic or idiosyncratic reactions to preparations of Technetium Tc 99m Albumin Aggregated have been reported.  

**PRECAUTIONS:**

General

The contents of the kit before preparation are not radioactive. However, after the addition of the pertechnetate Tc 99m, additional 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 peroxidase are added. Aspirin, epinephrine, antihistamines, and corticosteroids should be available for treatment.

The intravenous administration of any particulate materials such as Albumin Aggregated imposes 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 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 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°C to 8°C and discarded 6 hours after reconstitution.

Technetium Tc 99m Albumin Aggregated Injection is physically unstable and consequently the particles settle 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 at site.

Do not use if clumping of the contents is observed.

Technetium Tc 99m Albumin Aggregated is used as well as other radioactive drugs must be handled with care. Once sodium pertechnetate Tc 99m is added to the vial, appropriate safety measures must be used to minimize radiation exposure to 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 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 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 teratogenic studies have not been conducted with Technetium Tc 99m Albumin Aggregated injection. It is also 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.

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

**NURSING MATERNES**

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 shunt, 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 hyperfunction. Instances of hemolytic or idiosyncratic reactions to preparations of Technetium Tc 99m Albumin Aggregated have been reported (see Warnings).

**NOW 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 in lyophilized form:

- Sterile albumin
- Non-pyrogenic:
  - Albumin Aggregated: 2.5 mg
  - Sodium Chloride (minimum): 5.0 mg
  - Maximum stannous and stannic chloride: 0.11 mg
  - Sodium chloride: 0.06 mg
  - Stannous Chloride: 1.2 mg

HQ or NaN has been used for pH adjustment. The vials are sealed under an atmosphere of nitrogen.

Twenty labels with radiation warning symbols and a package insert are supplied in each carton.