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DESCRIPTION
Macrotec is a sterile, nonpyrogenic, lyophilized preparation of albumin aggregated. Each 5 mL vial of Macrotec contains 1.5 mg of Albumin Aggregated, 10.0 mg Albumin Human, 0.06 mg (minimum) stannous chloride (maximum stannic chloride 0.16 mg), 1.8 mg of sodium chloride with trace amounts of sodium acetate, acetic acid and hydrochloric acid. Macrotec contains no preservatives. The pH of the reconstituted product is between 3.6 and 8.0.

The aggregated particles are formed by denaturation of Albumin Human in a heating and precipitation process. Each vial contains 1-8 million particles, 90% of which are between 10 and 90 microns in size. The average size is 20 to 40 microns; no particles are greater than 150 microns.

Reconstitution of Macrotec with sterile sodium pertechnetate Tc 99m forms an aqueous suspension of Technetium Tc 99m Albumin Aggregated for diagnostic use by Intravenous injection. No less than 90% of the pertechnetate Tc 99m added to the reaction vial is bound to the aggregates at preparation time and remains bound throughout the 6-hour lifetime of the suspension.

INDICATIONS AND USAGE
Lung Imaging
Macrotec (Technetium Tc 99m Albumin Aggregated Injection) is a lung imaging agent which may be used as an adjunct in the evaluation of pulmonary perfusion in adults and children. It is useful in the early detection of pulmonary emboli and in the evaluation of the status of the pulmonary circulation in such conditions as pulmonary neoplasm, pulmonary tuberculosis and emphysema.

Isotopic Venography
Macrotec is also indicated for use in isotopic venography as an adjunct in the screening, diagnosis and management of deep vein thrombosis in the lower extremities.

Combined isotopic venography of the lower extremities and the pulmonary vasculature may be performed.

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
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 idiosyncratic reactions to preparations of Technetium Tc 99m Albumin Aggregated have been reported.

PRECAUTIONS
General
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 pertechnetate labeled Albumin Aggregated are used in man. Epinephrine, antihistamines and corticosteroids should be kept available for immediate use.

The Intravenous administration of any particulate material 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 cor pulmonale and other states of severely impaired pulmonary blood flow.

The components of the Macrotec (Technetium Tc 99m Albumin Aggregated Kit) are sterile and non-pyrogenic. It is essential to follow directions carefully and adhere to strict aseptic procedures during preparation.

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

The technetium Tc 99m labeling reactions involved depend on maintaining the stannous ion in the reduced state. Hence, sodium stannous chloride 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 formulation.

Technetium Tc 99m Albumin Aggregated Injection is a physically unstable suspension 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.

Radiopharmaceuticals must 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 other radioactive material, care should be taken to minimize radiation exposure to patients consistent with proper patient management, and to minimize radiation exposure to clinical personnel.

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 teratogenicity 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 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 the right-to-left shunting, in neonates and in severe pulmonary disease.

ADVERSE REACTIONS
Although adverse reactions specifically attributable to the 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. Instances of hemodynamic or idiosyncratic reactions to preparations of Technetium Tc 99m Albumin Aggregated have been reported.

HOW SUPPLIED
Macrotec (Technetium Tc 99m Albumin Aggregated) is supplied as a kit containing 10 reaction vials (5 mL size).
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Physician

NUCLEAR MEDICINE PHYSICIAN wanted. Well trained and experienced Board Certified Nuclear Medicine Physician with Board Certification or Board Eligible in internal medicine who has been in solo practice of nuclear medicine (non-subsidized) for 5-10 years who would be interested in becoming a partner in a successful privately owned outpatient Nuclear Medicine Clinic and lab, fully equipped for in vivo and in vitro studies. Includes private office with Technical and Administrative Staff. Must be willing and capable of assuming administrative and technical responsibility. Medical school affiliation possible if desired. Please send resume to: Box 201, Society of Nuclear Medicine, 475 Park Ave. So., New York, NY 10016.

NUCLEAR MEDICINE STAFF PHYSICIAN. Nuclear Medicine Dept. in large private Southern California hospital desires boarded or eligible associate. Applicant should be well-versed in current techniques including cardiovascular nuclear medicine. Computer aptitude and experience desirable. Opportunity for clinical research if desired. Please send typed resume and brief handwritten statement of career goals to: Box 202, Society of Nuclear Medicine, 475 Park Ave. So., New York, NY 10016. All inquiries will be kept confidential.

EXCELLENT PHYSICIAN OPPORTUNITY to join nuclear medicine/diagnostic ultrasonic group in South Florida. Special emphasis on cardiovascular nuclear medicine and echocardiography. Send CV to: Drs. Gottlieb and Block, 1150 N. W. 14th St., Suite #1, Miami, FL 33136; (305)324-0424.

RADIOLOGIST TO JOIN 7-MAN DYNAMIC, specialist private practice group in a 517-bed hospital in suburban New Orleans. Applicant needs Board certification in radiology and either certification or special competence in nuclear medicine. Nuclear Medicine Section is well-equipped with emphasis on nuclear cardiology. Please send resume to: G.S. Harel, MD, Dept. of Radiology, Eastern General Hospital, 4200 Houma Blvd., Metairie, LA 70011.

STAFF POSITION, ASSISTANT/ASSOCIATE Professor. Dual appointment—nuclear medicine/cardiology. Must have nuclear medicine and cardiology boards. Teaching and research experience necessary. Active clinical and teaching cardiovascular cardiology services with state-of-the-art equipment. Reply to: Michael E. Siegel, MD/Shahbodin Rahimtoola, MD, LAC/USC Medical Center, Box 693, 1200 North State St., Los Angeles, CA 90033.

Scientist

PHYSICIST/COMPUTER SCIENTIST. Medical College of Virginia-Virginia Commonwealth University has an immediate opening for a Physicist/Computer Scientist in nuclear medicine. Responsibilities include participation in current clinical and basic research programs and development of software algorithm and image processing techniques. Available equipment includes SPECT camera, DEC PDP 11/34 and VAX 780 computers. Send resume to: Dr. Melvin J. Fraktin, Medical College of Virginia, MCV Station Box 481, Richmond, VA 23298. MCV/VCU is an Equal Opportunity Employer.

CLINICAL NUCLEAR MEDICINE IMAGING PHYSICIST. The Department of Diagnostic Radiology has an opening for a Medical Physicist. This clinically funded position includes an appointment in diagnostic radiology with a primary commitment to nuclear medicine. Applicant must have general nuclear medicine and nuclear cardiology and an opportunity to participate in academic programs. Candidates should have a PhD or similar degree in the physical sciences with previous clinical nuclear experience and be Board certified or eligible. Although experience in nuclear cardiology is preferred, a desire to participate in nuclear cardiology is essential. Responsibilities include physics support of clinical procedures; development in testing of phantoms for optimization of patient studies; and education including the development of appropriate laboratories. Qualified applicants should forward a curriculum vitae and cover letter highlighting their qualifications and career goals to: Dr. Joel E. Grey, Mayo Clinic, Rochester, MN 55905. The Mayo Clinic is an Equal Opportunity and Affirmative Action Institution.

Technologist

NUCLEAR MEDICINE TECHNOLOGIST and/or Ultrasound Technologist (registered) needed for 99-bed hospital in Rocky Mountain University town of 24,000. Skiing, fishing, hunting close. Metro Denver within 2½ hours. Good working conditions/benefits. Salary negotiable. Send resume to: Personnel, Iverson Memorial Hospital, 225 North 30th, Laramie, WY 82070.

FACULTY—NUCLEAR MEDICINE TECHNOLOGIST. Tenure track faculty position with responsibilities for teaching in the university setting and supervision/liaison of the training program at affiliated clinical sites. Minimum qualifications include an MS in clinical sciences or a doctorate in a closely related field, certification or licensure in nuclear medicine technology, experience as a licensed or certified laboratory, and teaching part- or full-time in a clinical or academic setting. Preference will be given to applicants also holding certification as Medical Technologists. Submit letter of application with resume to: Dr. James L. Welch, School of Science, Mathematics, and Technology, California State University, Dominguez Hills, 1000 E. Victoria St., Carson, CA 90747; (213)516-3740. Application deadline: 4/30/85.

NUCLEAR MEDICINE TECHNOLOGIST. Large university teaching hospital has immediate opening for a registered or registry eligible Nuclear Medicine Technologist. Experience desirable. Send resume to: Personnel Department, University of Rochester, Box 636L, 260 Crittenden Boulevard, Rochester, NY 14642. Equal Opportunity Employer M/F.

NUCLEAR MEDICINE TECHNOLOGIST. Registered Nuclear Med. Technologists needed for private expanding nuclear medicine/diagnostic ultrasonic lab in South Florida. Special emphasis on cardiovascular procedures and computer processing techniques. Send resume to: Drs. Gottlieb and Block, 1150 N. W. 14th St., Suite #1, Miami, FL 33136; (305)324-0424.

Positions Wanted

Technologist

NUCLEAR MEDICINE TECHNOLOGIST. 1 year work experience, BS degree, ARRT registered. Interested in Philadelphia area. Please call: John, (215)277-5993.

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