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TECHNETIUM Tc 99m GENERATOR for the Production of Sodium Pertechnetate Tc 99m

DESCRIPTION: The Technetium Tc 99m Generator is prepared with fission produced Molybdenum Mo 99 absorbed on aluminum in a lead-shielded column and provides a means for obtaining sterile syringe-line solutions of Sodium Pertechnetate Tc 99m in sodium chloride injection. The eluate should be crystal clear. With a pH of 4.5-7.5, hydrochloric acid and/or sodium hydroxide may be used for pH adjustment. Over the life of the generator, an elution will contain a yield of 80% to 100% of the theoretical amount of Technetium Tc 99m available from the Molybdenum Mo 99 generator column.

Each eluate of the generator should not contain more than 0.15 microcuries of the Molybdenum Mo 99 per milliliter of Technetium Tc 99m per administered dose at the time of administration, and not more than 10 micrograms of aluminum per milliliter of the generator eluates, both of which must be determined by the user before administration.

INDICATIONS AND USAGE: Sodium Pertechnetate Tc 99m is used in ADULTS as an agent for: brain imaging including cerebral radionuclide angiography; thyroid imaging; salivary gland imaging; patients localization; blood pool imaging including radionuclide angiography, and urinary bladder imaging (direct isotopic cystography) for detection of vesico-urethral reflux.

Sodium Pertechnetate Tc 99m is used in CHILDREN as an agent for: brain imaging including cerebral radionuclide angiography; thyroid imaging; blood pool imaging including radionuclide angiography, and urinary bladder imaging (direct isotopic cystography) for the detection of vesico-urethral reflux.

CONTRAINDICATIONS: None known

WARNINGS: Radiation risks associated with the use of Sodium Pertechnetate Tc 99m are greater in children than in adults. In general, the younger the child the greater the risk owing to greater absorbed radiation doses and longer life expectancy. These greater risks should be taken firmly into account in all benefit-risk assessments involving children.

PRECAUTIONS: 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.

Carcinogenesis, Mutagenesis, Impairment of Fertility:
No long-term animal studies have been performed to evaluate carcinogenic potential or whether Technetium Tc 99m may affect fertility in males or females.

Pregnancy Category C

Animal reproductive studies have not been conducted with Technetium Tc 99m. It is also not known whether Technetium Tc 99m can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Technetium Tc 99m should be given to a pregnant woman only if the expected benefits are thought to be greater than the potential hazards. Women of childbearing age should be advised of the potential hazard to the fetus.

ADVERSE REACTIONS: Allergic reactions including anaphylaxis have been reported infrequently following the administration of Sodium Pertechnetate Tc 99m.

HOW SUPPLIED: Sodium Pertechnetate Tc 99m is supplied as a Molybdenum Mo 99/Technetium Tc 99m generator in packs from 500 microcuries up to 16,000 microcuries in approximately 830 millicuries increments of Molybdenum Mo 99 as of 10:00 P.M. Eastern Standard Time of the day of calibration. The TECHNETIUM Tc 99m GENERATOR consists of:

1) sterile generator, 2) Sodium Chloride Injection source, 3) 10 cc sterile evacuated vials, 4) sterile needles, 5) elution vial shield® 6) lindane drug tablets. Elution vials in 5 cc and 20 cc sizes are available upon request.

Initial order only

The TECHNETIUM Tc 99m GENERATOR should not be used after 16 days from the date and time of calibration.

Jointly manufactured by:
CINTICHEM, INC. and
UNION CARBIDE CORPORATION
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June, 1983
Early assessment of suspected neurologic disorders continues to pose important clinical challenges – challenges largely unmet by the restricted availability of positron-emission tomography (PET) and the acknowledged limitations of transmission computed tomography and SPECT as performed by rotating gamma-cameras. Noninvasive single-photon emission computed tomography (SPECT) can provide highly sensitive, early diagnostic information useful in the management of the hundreds of thousands of patients who each year develop central nervous system disease.

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In therapeutic monitoring: SPECT imaging enables clinicians to assess normalization following medical or surgical therapy.

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For further information please contact:

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The most important instrument in your department may be the telephone. Unless it rings—unless clinicians refer patients for studies—there is no nuclear medicine practice.

Under today's DRG-based payment systems, obtaining and maintaining referrals has become even more important. Hospitals are encouraging their clinicians to minimize the number of tests they order, selecting those that are most definitive, that answer the diagnostic question in the shortest time, at the lowest cost.

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In addition, the Clinician's Guide contains information useful to the nursing staff in preparing and managing patients before and after their nuclear medicine studies. Ask your NEN/Du Pont representative how you can obtain copies of the Clinician's Guide for your hospital. And ask about our other programs to keep the phone ringing in your department. Our goal is Improving Excellence: enhancing the image of your department while improving the images in your department.

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Fundamentals of Nuclear Medicine

Edited by
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208 pp; 6 × 9" softcover
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Organ Imaging With Radionuclides
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9. Skeletal System
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Appendix
Glossary
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Please see following page for brief prescribing information.
Before the PUIMOLITE
The hypersensitivity reactions to Technetium Tc 99m have been reported.

Contraindications: Technetium Tc 99m aggregated albumin should not be administered to patients with severe pulmonary hypertension.

The use of Technetium Tc 99m aggregated albumin is contraindicated in persons with a history of hypersensitivity reactions to products containing human serum albumin.

Warnings: The possibility of allergic reactions should be considered in patients who receive multiple doses.

Theoretically, the intravenous administration of particulate material such as aggregated albumin imposes a temporary small mechanical impediment to blood flow. While this effect is probably physiologically insignificant in most patients, the administration of aggregated albumin is possibly hazardous in acute cor pulmonale and other states of severely impaired pulmonary blood flow.

Precautions: In cases of right to left cardiac shunt, additional risk may exist due to the rapid entry of aggregated albumin into systemic circulation.

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

Technetium Tc 99m Aggregated Albumin, as well as any radioactive drug, 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.

Technetium Tc 99m Aggregated Albumin should be formulated within eight (8) hours prior to clinical use.

Carcinogenesis, Mutagenesis, Impairment of Fertility

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

Pregnancy Category C

Animal reproductive studies have not been conducted with Technetium Tc 99m Aggregated Albumin. It is also not known whether Technetium Tc 99m Aggregated Albumin can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Technetium Tc 99m should be given to a pregnant woman only if clearly needed.

Pediactric use

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.

Adverse Reactions: The literature contains reports of deaths occurring after the administration of aggregated albumin to patients with pre-existing severe pulmonary hypertension. Instances of hemodynamic or idiosyncratic reactions to preparations of Tc 99m-labeled aggregated albumin have been reported.

Hypersensitivity reactions are possible whenever protein-containing materials such as Technetium Tc 99m-labeled aggregated albumin are used in man. Epinephrine, antihistamines, and corticosteroids should be available for use.

Dosage and Administration: The recommended intravenous dose range for the average patient (170 kg) is 1 to 4 milliliters. The volume of the dose may vary from 0.2 to 1.3 ml.

The recommended number of aggregated albumin particles to be administered per dose is 200,000 to 700,000 with the suggested number being approximately 350,000.

For ease and accuracy in dispensing the prepared agent, it is recommended that prior to reconstitution, concentrated sodium pertechnetate Tc 99m be further diluted to a volume of 8ml with fresh, preservative-free sodium chloride injection (USP).

The patient dose should be measured by a suitable radioactivity calibration system immediately prior to administration. Radiochemical purity should be checked prior to patient administration (Please see complete prescribing information.)

Now supplied: PULMOLITE® Technetium Tc 99m Aggregated Albumin Kit is supplied in kits of five or thirty vials, sterile and non-pyrogenic, each vial containing lyophilized form. Aggregated albumin (human) 1.0mg Normal human serum albumin 10mg Sodium chloride 10mg Stannous chloride (SnCl2) 2H2O (maximum) 0.07mg Each vial contains 3.66 x 108 aggregated albumin particles.

Before reconstitution store at room temperature 15° - 30°C.

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The components of the Technetium Tc 99m Aggregated Albumin 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 addition of pertechnetate solution and the withdrawal of doses for patient administration.

Technetium Tc 99m Aggregated Albumin is prepared by adding 2-8ml of oxidant-free sodium pertechnetate Tc 99m solution to the vial and swirling for about one minute. Shielding should be utilized when preparing the Technetium Tc 99m Aggregated Albumin.

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Peter T. Kirchner, M.D., Editor

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6 x 9'' softcover; 272 pp; 1984;
$22.00 SNM members, $29.00 non-members

Functional Mapping of Organ Systems
Covers important areas of computer software development in nuclear medicine such as functional mapping of organ systems and the cardiac system. Background subtraction, computed tomography, and image display techniques are also included, making this book useful to a wide audience of physicians, medical research scientists, and computer specialists.

6 x 9'' softcover; 272 pp; 1981;
$19.00 SNM members, $28.00 non-members

Emission Computed Tomography: Current Trends
Summarizes the current state-of-the-art in emission computed tomography, highlighting the recent shift in emphasis from multipinhole and rotating slant-hole collimators to rotating scintillation cameras. Original research papers and comprehensive review articles examine the basic mathematics and physics of ECT, problems of system performance and quality assurance, practical issues associated with clinical applications of SPECT, and various aspects of data processing.

6 x 9'' softcover; 320 pp; 1983;
$20.00 SNM members, $27.00 non-members

Single Photon Emission Computed Tomography and Other Selected Computer Topics
Describes a variety of SPECT techniques, including angled, parallel-hole, and seven-pinhole collimators, Pho/Con instruments, and Fourier techniques. Computer analysis of cardiac studies, data acquisition and storage methods, Anger camera evaluation, and whole-body counting are explored. In addition to a review of various algorithms and currently available computer systems, SPECT offers a performance comparison of instruments.

6 x 9'' softcover; 252 pp; 1980;
$18.00 SNM members, $27.00 non-members

Digital Imaging: Clinical Advances in Nuclear Medicine
Reviews a broad range of topics related to digital imaging such as renal function, time-domain imaging, cardiac imaging, tomography, optical memories, and system architecture. Clinicians and scientists in nuclear medicine and radiology, as well as those individuals involved in industry and academia, will benefit from this detailed examination.

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CONTRIBUTORS


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INDICATIONS AND USAGE: Technetium Tc 99m Sulfur Colloid Injection is used as an agent for imaging areas of functioning reticuloendothelial cells in the liver, spleen, and bone marrow.

CONTRAINDICATIONS: None known.

WARNINGS: The contents of the two syringes, one syringe containing the sodium thiostannate solution and the second syringe containing the appropriate buffer solution, are intended only for use in the preparation of the Technetium Tc 99m Sulfur Colloid Injection and are not to be directly administered to the patient.

The contents of the kit are not radioactive. However, after the Sodium Pertechnetate Tc 99m is added, adequate shielding of the final preparation must be maintained.

PRECAUTIONS: The components of the kit are sterile and pyrogen-free. It is essential that the user follows the directions carefully and adheres to strict aseptic procedures during preparation of the colloid.

The stability of the colloidal preparation may be decreased in the presence of polyvalent cations, thus resulting in the agglomeration of the individual colloidal particles. These larger particles are likely to be trapped by the pulmonary capillary bed following intravenous injection.

It is recommended that Sodium Pertechnetate Tc 99m solutions containing more than 10 micrograms/ml of aluminium ion not be used for formulation of the Technetium Tc 99m Sulfur Colloid Injection. The Sodium Pertechnetate Tc 99m solution must also be free of any traces of oxidizing agents such as peroxides and hypochlorites.

Technetium Tc 99m Sulfur Colloid Injection is physically unstable and as such the particles will settle with time. Failure to agitate the vial adequately before use may result in non-uniform distribution of radioactivity.

It is also recommended that because of the increasing probability of agglomeration with aging, a batch of Technetium Tc 99m Sulfur Colloid Injection not be used after six hours from the time of formulation.

The preparation contains no bacteriostatic preservative.

Pregnancy Category C. Animal reproduction studies have not been conducted with Technetium Tc 99m Sulfur Colloid. It is also not known whether Technetium Tc 99m Sulfur Colloid can cause fetal harm when administered to pregnant women or can affect reproduction capacity. Technetium Tc 99m Sulfur Colloid should be given to a pregnant woman only if clearly needed.

Ideally, examinations using radiopharmaceuticals, especially those elective in nature, or a woman of childbearing capability should be performed during the first 14 days following the onset of menstural bleeding.

It is not known whether this drug is excreted in human milk. As a general rule, nursing should not be undertaken while the patient is on a drug since many drugs are excreted in human milk.

Safety and effectiveness in children have not been established. Technetium Tc 99m Sulfur Colloid Injection, as well as other radioactive drugs, must be handled with care and appropriate safety measures should be used to minimize external radiation exposure to clinical personnel. Also, care should be taken to minimize radiation exposure to patients, consistent with proper patient management.

ADVERSE REACTIONS: Hypersensitivity reactions, including anaphylaxis, have been reported in patients receiving sulfur colloid preparations.

One death and several cases of lung and soft tissue uptake other than RES have been reported in the association with the use of Technetium Tc 99m Sulfur Colloid Injection.

HOW SUPPLIED: The TECHNETIUM 99m SULFUR COLLOID KIT is supplied as a sterile pyrogen-free kit consisting of five reaction vials, each containing 0.5 ml 1.0 N hydrochloric acid in water; five sterile syringes (labeled "A"), each containing 1.3 mg sodium thiostannate anhydrous in 1.7 ml aqueous solution; five sterile syringes (labeled "B"), each containing 26 mg neomycin in 5.1 ml aqueous buffer solution containing 277 mg sodium acetate anhydrous.

STORAGE: Store finished drug at room temperature.
Radiochemistry Related to Life Science
Edited by
G. L. STÖCKLIN, Jülich/Köln (FRG) - A. P. WOLF, Brookhaven (U.S.A.)

SPECIAL ISSUE of
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For complete prescribing information consult package insert, a summary of which follows:

DESCRIPTION: Each reagent ampul of the kit contains 2.2 ml of a sterile, pyrogen-free aqueous solution containing 1.3 mg of succimer and 0.42 mg of anhydrous stannous chloride in aqueous solution under a nitrogen gas atmosphere. When sterile, oxidant-free, pyrogen-free sodium perchlorate Tc 99m in sterile saline is combined with the reagent, following the instructions provided with the kit, a complex is formed. Administration is by intravenous injection for diagnostic use.

The succimer component of MPI Kidney Reagent consists of more than 90% meso isomer and less than 10% d,l isomer.

INDICATIONS AND USAGE: MPI DMSA Kidney Reagent is to be used as an aid in the scintigraphic evaluation of renal parenchymal disorders.

CONTRAINdications: None known.

WARNINGS: None.

PRECAUTIONS:

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.

Carcinogenesis, Mutagenesis, Impairment of Fertility: No long-term animal studies have been performed to evaluate carcinogenesis potential or whether Technetium Tc 99m Succimer affects fertility in male or females.

Pregnancy Category C: Animal reproduction studies have not been conducted with the MPI DMSA Kidney Reagent either with or without Tc 99m.

It is known whether Technetium Tc 99m alone or with Succimer can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Technetium Tc 99m should be administered 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, formul feeding should be substituted for breast-feeding.

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

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

MPI DMSA Kidney Reagent should be formulated within 30 minutes prior to clinical use. The product must be used within 30 minutes after preparation. Any unused portion should be discarded after that time.

Some patients with advanced renal failure may exhibit poor renal intake of Tc 99m DMSA. It has been reported that satisfactory images may be obtained in some of these patients by delaying imaging for up to 24 hours.

ADVERSE REACTIONS: Rare instances of syncope, fever, nausea and maculopapular skin rash have been reported.

HOW SUPPLIED: Each kit package contains the following components:

(1) Three sealed glass reagent ampuls, each containing 2.2 ml of sterile, pyrogen-free aqueous solution of 1.3 mg succimer and 0.42 mg anhydrous stannous chloride. The solution is under a nitrogen gas atmosphere.

(2) Three sterile and pyrogen-free mixing vials (10 ml).

(3) Three mixing vial labels.

(4) Six courtesy record labels.

(5) One package insert.