When You're Looking At The Thyroid,

Get A Better Look.
Sodium Iodide I 123.

1. Radioiodine is trapped by the thyroid and \textit{organified} in the synthesis of thyroxine.\textsuperscript{1,4} \textsuperscript{99m}TcO\textsubscript{4} is trapped, but not \textit{organified}, by the thyroid. Consequently, Tc\textsuperscript{99m} activity does not always indicate the physiologic condition of the thyroid.

2. Radioiodine clearly demonstrates the "cold" nonfunctioning nodules that may be associated with malignant thyroid tumors. Such nonfunctioning nodules have appeared "hot" or "cold" on images obtained with Tc\textsuperscript{99m}, necessitating a confirmatory radioiodine scan.\textsuperscript{2,3}

3. Radioiodine thyroid imaging is preferred to Tc\textsuperscript{99m} for investigation of patients with possible retrosternal thyroid tissue or in those patients whose images are unsatisfactory with Tc\textsuperscript{99m} due to poor radionuclide concentration.\textsuperscript{4}


\textsuperscript{2}Arnold, J. et al: \textsuperscript{99m}Tc-Pertechnetate Thyroid Scintigraphy in Patients Predisposed to Thyroid Neoplasms by Prior Radiotherapy to the Head and Neck. \textit{Radiology} 115:653-657, June 1975.


\textsuperscript{4}Arnold, J.E, Pinsky, S: Comparison of \textsuperscript{99m}Tc and \textsuperscript{123}I for Thyroid Imaging. \textit{J. Nucl. Med.}, 17:261, 1976.
Sodium Iodide 123: Clearly Different

**WHOLE BODY ABSORBED RADIATION DOSE**

<table>
<thead>
<tr>
<th>Iodine 123</th>
<th>Tc99m 3mCi</th>
</tr>
</thead>
<tbody>
<tr>
<td>100 μCi Capsule</td>
<td>(Resting population)</td>
</tr>
<tr>
<td>.006 - .012 rads</td>
<td>.042 rads</td>
</tr>
</tbody>
</table>

A female patient presented palpable nodes in the right side of the neck. A scan was performed with 20mCi of Technetium 99m (above left) which revealed an essentially normal scan. A 100μCi I 123 (above right) scan imaged a “cold” nodule in the lower right lobe of the thyroid and also imaged iodine concentrating tissue in the lymph nodes. The I 123 scan ruled out a diagnosis of lymphoma, but confirmed a diagnosis of thyroid carcinoma. Surgery revealed a follicular adenocarcinoma of the thyroid gland with extensive lymph node metastasis.

**DESCRIPTION:** Sodium iodide I 123 for diagnostic use is supplied as capsules and in vials as an aqueous solution for oral administration. At calibration time, each capsule has an activity of 100 microcuries and each vial contains a total specific concentration of two millicuries per ml.

**INDICATIONS:** Sodium iodide I 123 is indicated for use in the diagnosis of thyroid function and imaging.

**CONTRAINDICATIONS:** None known.

**WARNINGS:** This radiopharmaceutical should not be administered to children or to patients who are pregnant or to nursing mothers unless the information to be gained outweighs the potential hazards. Ideally, examinations using radiopharmaceuticals, especially those elective in nature, in women of childbearing capability should be performed during the first few (approximately 10) days following the onset of menses. However, when studies of thyroid function are clinically indicated for members of these special population groups, use of I 123 would be preferable to the use of I 131 in order to minimize radiation dosage.

Adequate reproduction studies have not been performed in animals to determine whether this drug affects fertility in males or females, has teratogenic potential, or has other adverse effects on the fetus. Sodium iodide I 123 should be used in pregnant women only when clearly needed.

**PRECAUTIONS:** Sodium iodide I 123, 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. The prescribed sodium iodide I 123 dose should be administered as soon as practicable in order to minimize the fraction of radiation exposure due to relative increase of radionuclidic contaminants with time. The uptake of I 123 may be decreased by recent administration of iodinated contrast materials, by intake of stable iodine in any form, or by thyroid, anti-thyroid, and certain other drugs. Accordingly, the patient should be questioned carefully regarding diet, previous medication, and procedures involving radiographic contrast media.

**ADVERSE REACTIONS:** There were nine adverse reactions reported in a series of 1,393 administrations. None of these were attributed to I 123. Five adverse reactions, consisting of gastric upset and vomiting, were attributed to a filler in the capsule. Two cases of headache and one case of nausea and weakness were attributed to the fasting state. One case of garlic odor on the breath was presumed to be attributable to the presence of tellurium.

**DOSEAGE AND ADMINISTRATION:** The recommended oral dose range for diagnostic studies of thyroid function in the average adult patient (70 kg) is from 100 to 400 microcuries. The patient dose should be measured by a suitable radioactivity calibration system immediately prior to administration. Concentration of I 123 in the thyroid gland should be measured in accordance with standardized procedures.

**SPECIAL CONSIDERATION:** 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.

**HOW SUPPLIED:** Sodium iodide I 123 for oral administration is supplied in aqueous solution in glass vials of 1mCi and in capsules of 100 μCi.
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(In Missouri, 314-895-2405 collect)

See brief summary on following page.

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BRIEF SUMMARY

CLINICAL PHARMACOLOGY

When injected intravenously TechneScan PYP Tc 99m has a specific affinity for areas of altered osteogenesis. It is also concentrated in the injured myocardium, primarily in areas of irreversibly damaged myocardial cells.

One to two hours after intravenous injection of TechneScan PYP To 99m, an estimated 40 to 50 percent of the injected dose has been taken up by the skeleton and approximately 0.01 to 0.02 percent per gram by acutely infarcted myocardium. Within a period of one hour, 10 to 11 percent remains in the vascular system, declining to approximately 2 to 3 percent twenty-four hours post-injection. The average urinary excretion was observed to be about 40 percent of the administered dose after 24 hours.

TechneScan PYP also has an affinity for red blood cells. When administered 30 minutes prior to the intravenous administration of sodium pertechnetate Tc 99m approximately 76 percent of the injected activity remains in the blood pool providing excellent images of the cardiac chambers.

INDICATIONS AND USAGE

TechneScan PYP Tc 99m is a skeletal imaging agent used to demonstrate areas of altered osteogenesis, and a cardiac imaging agent used as an adjunct in the diagnosis of acute myocardial infarction.

As an adjunct in the diagnosis of confirmed myocardial infarction (ECG and serum enzymes positive), the incidence of false negative images has been found to be 6 percent. False negative images can also occur if made too early in the evolutionary phase of the infarct or too late in the resolution phase. In a limited study involving 22 patients in whom the ECG was positive and serum enzymes questionable or negative, but in whom the final diagnosis of acute myocardial infarction was made, the incidence of false negative images was 23 percent. The incidence of false positive images has been found to be 7 to 9 percent. False positive images have also been reported following coronary by-pass graft surgery, in unstable angina pectoris, old myocardial infarcts and in cardiac contusions.

TechneScan PYP is a blood pool imaging agent which may be used for gated cardiac blood pool imaging. When administered intravenously 30 minutes prior to the intravenous administration of sodium pertechnetate Tc 99m approximately 76 percent of the injected activity remains in the blood pool.

CONTRAINDICATIONS

None.

WARNINGS

This radiopharmaceutical should not be administered to patients who are pregnant or lactating unless the information to be gained outweighs the potential hazards.

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.

Warning: Preliminary reports indicate impairment of brain scans using pertechnetate Tc-99m which have been preceded by bone scan. The impairment may result in false positives or false negatives. It is recommended, where feasible, that brain scans precede bone imaging procedures.

Radio pharmaceuticals should be used only by physicians who are qualified by specific training in the safe use and handling of radioisotopes produced by nuclear reactor or particle accelerator and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides.

The TechneScan PYP Kit must be maintained at refrigerator temperature until use.

The contents of the TechneScan PYP reaction vial are intended for use in the preparation of Technetium Tc 99m Stannous Pyrophosphate. TechneScan PYP may also be reconstituted with sterile, pyrogen-free normal saline containing no preservatives and injected intravenously prior to the administration of sodium pertechnetate Tc-99m.

Sodium pertechnetate Tc-99m solutions containing an oxidizing agent are not suitable for use with the TechneScan PYP Kit.

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.

TechneScan PYP Tc 99m should not be used more than six hours after preparation.

PRECAUTIONS

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

Bone Imaging

Both prior to and following TechneScan PYP Tc 99m administration, patients should be encouraged to drink fluids. Patients should void as often as possible after the TechneScan PYP Tc 99m injection to minimize background interference from accumulation in the bladder and unnecessary exposure to radiation.

Cardiac Imaging

Patient’s cardiac condition should be stable before beginning the cardiac imaging procedure.

If not contraindicated by the cardiac status, patients should be encouraged to ingest fluids and to void frequently in order to reduce unnecessary radiation exposure.

Interference from chest wall lesions such as breast tumors and healing rib fractures can be minimized by employing the three recommended projections.

Blood Pool Imaging

TechneScan PYP should be injected by direct venipuncture. Heparinized catheter systems should be avoided.

ADVERSE REACTIONS

None.

HOW SUPPLIED

Catalog Number—094 TechneScan PYP Tecnetium Tc 99m Pyrophosphate Kit.

Kit Contains:

5—Stannous Pyrophosphate Reaction Vials (lyophilized) for the preparation of Technetium Tc-99m Stannous Pyrophosphate.

Reaction Vial Contains:

12.0 mg sodium pyrophosphate and 3.4 mg stannous chloride (lyophilized). Hydrochloric acid is added for pH adjustment prior to lyophilization.

5—Radioassay Information String Tags.

For complete prescribing information, see package insert.
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The case of the double standard.

There is a double standard in HCG RIA. The World Health Organization established the 1st International Reference Preparation (1st IRP) 75/537 specifically for use in immunoassay. It is the purest HCG standard available. However, most radio-immunoassay kits are calibrated against the earlier WHO standard for bioassay, the 2nd International Standard (2nd IS). Hence, the double standard. Eventually, all HCG RIA Kits will be calibrated against the 1st IRP.

We use the purest standard. Clinical Assays’ GammaDab® β-HCG RIA Kit is calibrated against the 1st IRP. Consequently, the kit reports about twice as many milli-International Units as will kits calibrated against the earlier standard. For instance, if our kit reports that a sample contains 200 mIU/ml, a kit calibrated against the 2nd IS will report only half that amount of HCG, or about 100 mIU/ml.

Don’t be misled by the numbers. Kits calibrated against the old standard are really less sensitive than they appear. For example, a claim of 5 mIU/ml sensitivity translates into about 10 mIU/ml sensitivity, according to the 1st IRP. And a pregnancy screening procedure that supposedly picks up positives at 30 mIU/ml actually only detects positives above 60 mIU/ml.

We’re twice as sensitive as we look. The sensitivity of the GammaDab β-HCG RIA Kit is 2 mIU/ml in terms of the 1st IRP (1 mIU/ml in terms of the 2nd IS). The cut-off for our screening procedure is 25 mIU/ml, or 12.5 mIU/ml according to the old standard. This lower cut-off level can be significant when early pregnancy detection is vital, as in cases of suspected ectopic pregnancy or threatened abortion.

Find out more about our kit. It is not only sensitive, it is also convenient. Write or call for more information or an evaluation kit. We’ll also be happy to tell you more about the double standard.

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You asked for optimum thallium-201 activity at time of use and we heard you. Now our 2.0 and 4.0 millicurie sources are precalibrated on additional days to make available the proper dosages when you need them.

<table>
<thead>
<tr>
<th>ACTIVITY AVAILABLE</th>
<th>MONDAY</th>
<th>TUESDAY</th>
<th>WEDNESDAY</th>
<th>THURSDAY</th>
<th>FRIDAY</th>
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<tr>
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<td>2.76 mCi</td>
<td>2.76 mCi</td>
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<td>5.52 mCi</td>
<td>5.52 mCi</td>
<td>5.52 mCi</td>
<td>4.40 mCi</td>
</tr>
</tbody>
</table>

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For technical assistance call 900-325-8181 toll-free (in Missouri, 314-895-2405 collect)

See brief summary on following page.

THE MALLINCKRODT COMMITMENT to Nuclear Medicine

MALLINCKRODT, INC., Post Office Box 5840, St. Louis, MO 63134

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THALLOUS CHLORIDE TI 201 INJECTION
Diagnostic—for Intravenous Use

Brief Summary—for full prescribing information consult package insert.

DESCRIPTION
Thallous Chloride Ti 201 injection is supplied in isotonic solution as a sterile, nonpyrogenic diagnostic radiopharmaceutical for intravenous administration. Each ml contains 1 mcg Thallous Chloride Ti 201 at calibration time made isotonic with 0.9% sodium chloride and preserved with 0.9% n/v benzoic alcohol. The pH is adjusted to between 4.5-7.0 with hydrochloric acid and/or sodium hydroxide. Thallium Ti 201 is provided as a sterile solution. It is essentially carrier-free and contains no more than 1.0% Thallium Ti 202 and no more than 1.0% Thallium Ti 203.

CLINICAL PHARMACOLOGY
Cartridge-type Thallous Chloride Ti 201 has been found to accumulate in viable myocardium in a manner analogous to potassium. Experiments employing labeled microspheres in human volunteers have shown that the myocardial distribution of Thallous Chloride Ti 201 correlates well with regional perfusion.

In clinical studies, thallium images show areas of infarction as “cold” or metabolically compromised regions which are confirmed by electrocardiographic and enzyme changes. Regions of transient myocardial ischemia corresponding to areas perfused by coronary arteries with partial stenoses have been visualized as cold spots when Thallium was administered in conjunction with an exercise stress test.

After intravenous administration, Thallous Chloride Ti 201 clears rapidly from the blood with minimal clearance by normal myocardium occurring at about ten minutes.

Five minutes after intravenous administration only 5-6% of injected activity remained in the blood. A subsequent disappearance curve was obtained with 91.5% of the blood radioactivity disappearing with a T½ of about 5 minutes. The remainder had a T½ of about 40 hours.

Approximately 4 to 6% of the injected dose was excreted in the urine in the first 24 hours. The whole body half-life of the urine was 2.8 ± 2.5 days. Kidney concentration was found to be about 3 percent of the injected activity and the specific content was 0.13 percent. Net thyroid activity was determined to be only 0.2 percent of the injected dose, and the activity disappeared in 24 hours. Friction and joule whole-body scans, it was determined that about 10 percent of the injected dose was in the large intestines and contiguous structures time, kidneys, autonomic mucosa.


INDICATIONS AND USE
Thallous Chloride Ti 201 may be useful in myocardial perfusion imaging and for the diagnosis and localization of myocardial infarction.

It may also be useful in conjunction with exercise stress testing as an adjunct in the diagnosis of ischemic heart disease (atherosclerotic coronary artery disease).

It is usually not possible to differentiate acute from old myocardial infarction, or to differentiate exactly between recent myocardial infarction and ischemia.

CONTRAINDICATIONS
None known.

WARNINGS
When studying patients suspected or known to have myocardial infarction or ischemia, care should be taken to assure continuous clinical monitoring and treatment in accordance with safe, accepted procedures. Exercise stress testing should not be performed only under the supervision of a qualified physician and in a laboratory equipped with appropriate reaccumulation and support apparatus.

PREGNANCY CATEGORY C
Adequate reproduction studies have not been performed in animals to determine whether this drug affects fertility in males or females, has teratogenic potential, or has other adverse effects on the fetus. Thallium Chloride Ti 201 should not be used in pregnant women except when benefits clearly outweigh the potential risks.

PRECAUTIONS
Ideally, examinations using radiopharmaceutical drug products—especially those effective in nature—without evidence of coldness capability should be performed during the first ten days following the onset of menstruation.

URINARY DISTRESS
It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, as a general rule nursing should not be undertaken when a patient is administered radiopharmaceutical material.

Safety and effectiveness in children have not been established.

CARCINOGENESIS
No long-term animal studies have been performed to evaluate carcinogenic potential.

Data are not available concerning the effect on the quality of Thallium Ti 201 scans of marked alterations in blood glucose, insulin or pH (such as is found in diabetes mellitus). Attention is directed to the fact that thallium is a potassium analog, and since the transport of potassium is affected by these factors, the possibility exists that thallium may intravenously be affected.

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

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

This drug should not be used six (6) days after the calibration date.

ADVERSE REACTIONS
Adverse reactions related to use of this agent have not been reported to date.

SIDE EFFECTS
Thallous Chloride Ti 201 injection is supplied as a sterile, nonpyrogenic solution for intravenous administration. Each ml contains 1 mcg Thallium Ti 201 at calibration time made isotonic with 0.9% sodium chloride and 0.9 percent n/v benzoic alcohol. The pH is adjusted to between 4.5-7.0 with hydrochloric acid and/or sodium hydroxide solution. Vials are available in the following quantities of radiocactivity: 2.0, and 4.0 millicuries of Thallium Ti 201.

The contents of the vial are radioactive. Adequate shielding and handling precautions must be maintained.
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*In a recent independent survey of 400 nuclear medicine departments. Data on file at Mallinckrodt.

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This section in the Journal of Nuclear Medicine contains "Positions Open," "Positions Wanted," "For Sale," and "Equipment Wanted" listings. Nondisplay "Positions Open" ads by members of the Society are billed at 70¢ per word for each insertion with no minimum rate. Nondisplay "Positions Wanted" ads by members and all nondisplay "Positions Open," "For Sale" and "Equipment Wanted" ads by members and nonmembers are charged at 90¢ per word. Display advertisements are accepted at $150 for ¼ page, $205 for ½ page, $325 for ¾ page, and $560 for a full page.

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THE MALLINCKRODT COMMITMENT

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Please refer to the brief prescribing information on the following page.
AN-Sulfur Colloid

Technetium Tc 99m Sulfur Colloid Kit

For complete prescribing information, consult the package insert, a summary of which follows.

Indications and Usage. Technetium Tc 99m Sulfur Colloid 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 unit-dose syringes are intended only for use in the preparation of Technetium Tc 99m Sulfur Colloid 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 must be maintained.

Precautions. Radiopharmaceuticals should be used only by physicians who are qualified by specific training in the safe use and handling of radionuclides and whose experience and training have been approved by the appropriate government agency.

The components of the kit are sterile and non-pyrogenic. The user must follow the directions carefully and adhere to strict aseptic procedures during preparation.

The stability of the colloidal preparation may be decreased in the presence of polyvalent cations, resulting in the agglomeration into larger particles which are likely to be trapped in the pulmonary capillary bed following intravenous injection. It is recommended that Sodium Pertechnetate Tc 99m solutions containing more than 10 micrograms/ml of aluminum ion not be used for reagent preparation. The pertechnetate solution must also be free of any traces of oxidizing agents.

Technetium Tc 99m Sulfur Colloid is physically unstable and the particles will settle with time. Failure to agitate the vial adequately before use may result in non-uniform distribution of radioactivity. Use within 8 hours after preparation.

No long-term animal studies have been performed to evaluate carcinogenic potential or whether Technetium Tc 99m Sulfur Colloid affects fertility in males and females. It is not known whether Technetium Tc 99m Sulfur Colloid can cause fetal harm when Sulfur Colloid is given to a pregnant woman. The preparation should be given to a pregnant woman only if clearly needed. Ideally, examinations using radiopharmaceuticals, especially those elective in nature, of a woman of child-bearing capability should be performed during the first few (approximately 10) days following the onset of menses.

It is not known whether this drug is excreted in human milk. A decision should be made whether to discontinue nursing or to discontinue the drug.

Safety and effectiveness in children have not been established.

Adverse Reactions. Hypersensitivity reactions, including anaphylaxis, have been reported in patients receiving sulfur colloid preparation. One death and several cases of lung and soft tissue uptake other than RES have been reported in association with the use of Technetium Tc 99m Sulfur Colloid.

Dosage and Administration. The suggested intravenous dose range used in the average (70 kg) patient is 1 to 8 millicuries of Technetium Tc 99m Sulfur Colloid. When orally administered, the preparation is not absorbed from the G.I. tract. The patient dose should be measured by a suitable radioactivity calibration system immediately prior to administration.

How Supplied. Each kit contains 5 complete preparations plus instructions and 10 radioactivity labels. Each preparation is separately packaged and contains a reaction vial made with sterile, non-pyrogenic freeze-dried materials consisting of sodium thiosulfate (anhydrous) 2.0 mg, edetate disodium 2.3 mg and gelatin 18.1 mg; an "A" syringe containing 1.5 ml of sterile, non-pyrogenic 0.148 N hydrochloric acid solution and a "B" syringe containing 1.5 ml of sterile, non-pyrogenic aqueous solution of sodium bisphosphate (anhydrous) 36.1 mg and sodium hydroxide 11.1 mg. Included in each preparation is one string label and two needles. Store kit contents at room temperature.

Catalog Number: K-601
Description: 5-preparation kit
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Sylmar, California 91342

---

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- SI-19 The Measurement of Ejection Fraction by William Ashburn, MD
- SI-20 Intracardiac Shunts and Cardiac Output by William Ashburn, MD
- SI-21 Perfusion Studies of the Ischemic Heart by Glen W. Hamilton, MD
- SI-22 Detection of Acute Myocardial Infarction by B. Leonard Holman, MD
- SI-23 Instrumentation for Nuclear Cardiology by Trevor D. Craddock, PhD

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Please send the following audiovisual units.

(Click units desired.)

<p>| | | |</p>
<table>
<thead>
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<td>SI-18</td>
<td>SI-20</td>
<td>SI-22</td>
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<td>SI-19</td>
<td>SI-21</td>
<td>SI-23</td>
</tr>
</tbody>
</table>

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Zip ______

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<table>
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<tr>
<th>Name</th>
<th>Title</th>
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<table>
<thead>
<tr>
<th>Name of Hospital or Firm</th>
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<table>
<thead>
<tr>
<th>Address</th>
<th>Zip Code</th>
<th>Phone</th>
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</table>

Approx. no. of RIAs (all types) done per month________________________

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THE

MALLINCKRODT

COMMITMENT

to Nuclear Medicine

MALLINCKRODT, INC., Post Office Box 5840, St. Louis, MO 63134

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**Technetium Tc 99m Medronate Sodium Kit**

**DIAGNOSTIC**

**DESCRIPTION**

The kit consists of reaction vials which contain the sterile, non-pyrogenic, non-radioactive ingredients necessary to produce technetium Tc-99m medronate for diagnostic use by intravenous injection.

Each 10 ml reaction vial contains 10 mg medronic acid complexed with 0.8 mg min (1 stannous chloride (0.64 mg maximum) for rapid precipitation of technetium Tc-99m as a water-soluble sodium complex with hydrochloric acid. Sodium hydroxide or hydrochloric acid will have been used for pH adjustments. The addition of sodium pertechnetate Tc-99m sterile solution produces a rapid labelling which is essentially quantitative and which remains stable at 37°C throughout the useful life of the preparation.

No bacteriostatic preservative is present.

The precise structure of the reaction vial complex or of its technetium labeled form is not known at this time.

**PHYSICAL CHARACTERISTICS**

Technetium Tc 99m decays by isomeric transition with a physical half-life of 6.02 hours. The principal photon that is useful for detection and imaging studies is listed in Table 1.

**TABLE I: PRINCIPAL RADIATION EMISSION DATA**

<table>
<thead>
<tr>
<th>Radiation</th>
<th>Mean % Disintegration</th>
<th>Mean Energy (keV)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gamma-2</td>
<td>88 96</td>
<td>140.5</td>
</tr>
</tbody>
</table>

**External Radiation**

The specific gamma ray constant for Tc-99m is 0.8 R/mCi-hr at 1 cm. The first half value layer is 0.2 mm of Pt. To facilitate control of the radiation exposure from micromicro Ci amounts of this radionuclide, use of a 2.7 mm thickness of Pt will attenuate the radiation emitted by a factor of about 1.000.

**TABLE II: RADIATION ATTENUATION BY LEAD SHIELDING**

<table>
<thead>
<tr>
<th>Shield Thickness (Pb) mm</th>
<th>Coefficient of Attenuation</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.2</td>
<td>0.5</td>
</tr>
<tr>
<td>0.95</td>
<td>10(^{+})</td>
</tr>
<tr>
<td>1.6</td>
<td>10(^{-})</td>
</tr>
<tr>
<td>2</td>
<td>10(^{+})</td>
</tr>
<tr>
<td>3</td>
<td>10(^{-})</td>
</tr>
<tr>
<td>4</td>
<td>10(^{+})</td>
</tr>
</tbody>
</table>

To correct for physical decay of this radionuclide, the fractions that remain at selected intervals after the time of calibration are shown in Table III.

**TABLE III: TECHNETIUM DECAY CHART: Tc 99m, half-life 6.02 hours**

<table>
<thead>
<tr>
<th>Hours Remaining</th>
<th>Fraction Remaining</th>
<th>Hours</th>
<th>Fraction Remaining</th>
</tr>
</thead>
<tbody>
<tr>
<td>-5</td>
<td>1778</td>
<td>5</td>
<td>0.562</td>
</tr>
<tr>
<td>-4</td>
<td>1585</td>
<td>6</td>
<td>0.501</td>
</tr>
<tr>
<td>-3</td>
<td>1413</td>
<td>7</td>
<td>0.447</td>
</tr>
<tr>
<td>-2</td>
<td>1259</td>
<td>8</td>
<td>0.398</td>
</tr>
<tr>
<td>-1</td>
<td>1122</td>
<td>9</td>
<td>0.355</td>
</tr>
<tr>
<td>0</td>
<td>1000</td>
<td>10</td>
<td>0.316</td>
</tr>
<tr>
<td>1</td>
<td>911</td>
<td>11</td>
<td>0.282</td>
</tr>
<tr>
<td>2</td>
<td>794</td>
<td>12</td>
<td>0.251</td>
</tr>
<tr>
<td>3</td>
<td>631</td>
<td>13</td>
<td>0.226</td>
</tr>
<tr>
<td>4</td>
<td>631</td>
<td>24</td>
<td>0.063</td>
</tr>
</tbody>
</table>

**CLINICAL PHARMACOLOGY**

When injected intravenously technetium Tc-99m medronate is rapidly cleared from the blood and accumulates in the skeleton and urine. The skeletal uptake is bilaterally symmetrical being greatest in the axial skeleton than in the long bones. Areas of abnormal osteogenesis show uptake making it possible to visualize a variety of osseous lesions.

Studies in humans show that, following intravenous injection, about 10% of the injected dose remains in the bloodstream at the end of one hour. This value continues to drop rapidly, being down to about 5% at 2 hours. The resultant disappearance curve appears to be tri-exponential, the two fast components accounting for all but a few percent of the injected activity.

Commonly, there is a rapid deposition in bone and rapid urinary excretion. The rapid blood clearance provides bone to soft tissue ratios which favor early imaging.

**INDICATIONS AND USAGE**

Technetium Tc-99m medronate is a skeletal imaging agent used to demonstrate areas of altered osteogenesis as seen for example in metastatic bone disease, Paget’s disease, arthritic disease and osteomyelitis.

**CONTRAINdications**

None known at present.

**WARNINGS**

This radiopharmaceutical should not be administered to children or to patients who are pregnant or to nursing mothers unless the benefits to be gained outweigh the potential hazards.

Ideally, examinations using radiopharmaceuticals, especially those electively in nature, in women of childbearing capability should be performed during the first few (approximately 10) days following the onset of menses. This class of compound is known to complex cations such as calcium. Particular caution should be used with patients who have, or who may be predisposed to, hypocalcemia (i.e., alkalosis).

**PRECAUTIONS**

General

The finding of an abnormal concentration of radioactivity implies the existence of underlying pathology, but further study is required to distinguish benign from malignant lesions.

Technetium Tc-99m medronate 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.

To minimize the radiation dose to the bladder, the patient should be encouraged to void before the examination and as often thereafter as possible for the next 4-6 hours.

The preparation contains no bacteriostatic preservative. Therefore, after labeling with technetium Tc-99m the solution should be stored at 2-8°C and discarded after 6 hours.

The image quality may be adversely affected by obesity, old age and impaired renal function.

**Carcinogenesis**

No long term animal studies have been performed to evaluate carcinogenic potential.

**Pregnancy**

Adequate reproductive studies have not been performed in animals to determine whether this drug affects fertility in males or females, has teratogenic potential, or has other adverse effects on the fetus. There have been no studies in pregnant women. Technetium Tc-99m medronate should be used in pregnant women only when clearly needed.

**Nursing Mothers**

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

**Pediatric Use**

Safety and effectiveness in children have not been established.

**ADVERSE REACTIONS**

At present adverse reactions have not been reported that are specifically attributable to the use of technetium Tc-99m medronate.

**DOSEAGE AND ADMINISTRATION**

The recommended adult dose is 10 to 20 mCi (200-400 mCi/kg) by slow intravenous injection over a period of 30 minutes. Optimum scanning time is 1 to 4 hours post-injection.

The patient should be encouraged to drink fluids before and after the examination to void immediately before imaging is started. This is to minimize the contribution of the bladder content to the image.

The patient dose should be measured by a suitable radioactivity calibration system immediately prior to administration.

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

**Radiation Dosimetry**

The estimated absorbed radiation doses due to an average patient (70 kg) from an intravenous injection of a maximum dose of 20 mCi of technetium Tc-99m medronate are shown in Table IV.

**Table IV: RADIATION DOES**

<table>
<thead>
<tr>
<th>Tissue</th>
<th>Absorbed Radiation Dose (rads/20 mCi)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Body</td>
<td>0.13</td>
</tr>
<tr>
<td>Bone Total</td>
<td>0.70</td>
</tr>
<tr>
<td>Kidneys</td>
<td>0.56</td>
</tr>
<tr>
<td>Liver</td>
<td>0.80</td>
</tr>
<tr>
<td>Bladder Wall</td>
<td>0.06</td>
</tr>
<tr>
<td>Ovaries</td>
<td>0.24</td>
</tr>
<tr>
<td>Testes</td>
<td>0.16</td>
</tr>
</tbody>
</table>

**HOW SUPPLIED**

TechnetScan MDP®-Technetium Tc 99m Medronate Sodium Kit.

Product No. 069

Each kit consists of 5 reaction vials, each vial containing, in hypotonic form, sterile and non-pyrogenic Medronic Acid 10 mg Stannous Chloride min 0.64 mg Maximum Lin 0.05 mg.

The pH is adjusted to 6.5 to 7.5 with HCl or NaOH prior to hypotonicization. The vials are sealed under an atmosphere of nitrogen.

Labels with radiation warning symbols and directions are supplied with each kit.

**DIRECTIONS**

**NOTE:** Use aseptic procedures throughout and take precautions to minimize radiation exposure.

To prepare technetium Tc 99m medronate:

1. Remove the central metal disc from a reaction vial and swab the closure with either an alcohol swab or a suitable bacteriostatic agent.
2. Place the vial in a suitable radiation shield. Obtain from a generator 2-10 ml of sterile, pyrogen-free sodium pertechnetate Tc-99m. The recommended maximum amount of technetium Tc-99m to be added to a reaction vial is 200 mCi. Sodium pertechnetate Tc-99m solutions containing an oxidizing agent are not suitable for use.
3. Add the sodium pertechnetate Tc-99m solution to the reaction vial aseptically.
4. Agitate the shielded vial until the contents are completely dissolved. The solution must be clear and free of particulate matter before proceeding.
5. Assay the product in a suitable calibrator, complete the radioassay information tie-on tag with radiation warning symbol and attach it to the vial.
6. Withdrawals for administration must be made aseptically using a sterile syringe and needle.
7. The finished preparation should be refrigerated at 2-8°C when not in use and discarded after 6 hours.

"This reagent kit is approved by the U.S. Nuclear Regulatory Commission for distribution to persons licensed pursuant to Sections 35.14 and 35.100. Group III. of 10 CFR Part 35, or under equivalent licenses of Agreement States."

Manufactured by: MALLINCKRODT, INC. St. Louis, Missouri 63134 U.S.A.

By: MERCK FROSST LABORATORIES S.R. Kirkland (Montreal), Canada

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Osteoscan-HDP represents a significant technological advance in bone scanning agents. Its unique new active ingredient, hydroxymethylene diphosphonate (HDP), provides higher bone uptake than MDP-based agents for clear, definitive scans and excellent lesion detection.

Bone uptake superior to MDP

HDP shows unusually high adsorption to bone. In a clinical comparison, Osteoscan-HDP averaged 21% higher bone uptake than the MDP-based agent.1

Scan data:
The two scans above are of a 56-year-old female patient with breast cancer. Scan: abnormal activity in right ischial ramus. Instrument: General Electric MaxiCamera™ 535; total counts: 2000K; dose: 20.8 mCi; 5'5", 175 lb; dose-to-image time: 2.25 hours
Notice excellent bone delineation in this obese patient.

Rapid blood clearance

No bone agent clears the blood faster. Only 6% of Osteoscan-HDP remains in the blood two hours after injection.2 Osteoscan-HDP’s rapid blood clearance contributes to the overall quality of the image and permits flexibility in scheduling patient scans from 1 to 4 hours post-injection.

References:
offering higher bone uptake

PROCTER & GAMBLE

OSTEOSCAN-HDP
Technetium Tc99m Oxidronate Kit

High lesion sensitivity
HDP offers a high tumor-to-normal bone ratio. This results in high resolution scans capable of demonstrating subtle skeletal metastases and fractures with no sacrifice in overall image quality.

Scan data:
The two scans above are of a 79-year-old male patient with adenocarcinoma-prostate. Scan: multiple lesions. Instrument: Picker 4/15 Gamma Camera; information density: 3000; dose: 15 mCi; dose-to-image time: 3 hours

Please see the following page for a brief summary of prescribing information.
OSTEOSCAN-HDP (Technetium Tc99m Oxidronate Kit) is a diagnostic skeletal imaging agent used to demonstrate areas of altered osteogenesis.

**CLINICAL PHARMACOLOGY**

During the 24 hours following injection, Technetium Tc99m-labeled OSTEOSCAN-HDP is rapidly cleared from blood and other non-osseous tissues and accumulates in the skeleton and urine. In humans, blood levels are about 10% of the injected dose at one hour post-injection and continue to fall to about 6%, 4%, and 3% at 2, 3, and 4 hours respectively. When measured at 24 hours following its administration, skeletal retention is approximately 50% of the injected dose. OSTEOSCAN-HDP exhibits its greatest affinity for areas of altered osteogenesis and actively metabolizing bone.

**CONTRAINDICATIONS**

None known.

**WARNINGS**

This class of compounds is known to complex cations such as calcium. Particular caution should be used with patients who have, or who may be predisposed to hypocalcemia (i.e., alkalosis).

**PRECAUTIONS**

**General**

Contents of the vial are intended only for use in the preparation of Technetium Tc99m Oxidronate and are NOT to be administered directly to the patient. Technetium Tc99m Oxidronate should be formulated within eight (8) hours prior to clinical use. Optimal imaging results are obtained one to four hours after administration.

Technetium Tc99m Oxidronate as well as other radioactive drugs, must be handled with care, and appropriate safety measures should be used to minimize radiation exposure to the patient consistent with proper patient management. Radiopharmaceuticals should be used only by physicians who are qualified by specific training 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.

To minimize radiation dose to the bladder, the patients should be encouraged to drink fluids and to void immediately before the examination and as often thereafter as possible for the next four to six hours.

**Carcinogenesis, Mutagenesis, Impairment of Fertility**

No long-term animal studies have been performed to evaluate carcinogenic potential or whether Technetium Tc99m Oxidronate affects fertility in males and females.

**Pregnancy — Category C**

Animal reproduction studies have not been conducted with Technetium Tc99m Oxidronate. It is also not known whether Technetium Tc99m Oxidronate can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Technetium Tc99m Oxidronate should be given to a pregnant woman only if clearly needed. Ideally, examinations using radionuclides, 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 Tc99m is excreted in human milk during lactation, therefore formula feedings should be substituted for breast feedings.

**Pediatric Use**

Safety and effectiveness in children have not been established.

**ADVERSE REACTIONS**

Although adverse reactions have not been reported that are specifically attributable to the use of Technetium Tc99m Oxidronate, allergic dermatological manifestations (erythema) have been infrequently reported with similar agents.

**DOSEAGE AND ADMINISTRATION**

**General Instructions**

The recommended adult dose of Technetium Tc99m-labeled OSTEOSCAN-HDP is 15 mCi with a range of 10 to 20 mCi. The activity of each dose should be measured by a suitable radiation calibration system just prior to administration. The dose should be given intravenously by slow injection. For optimal results imaging should be done 1-4 hours post-injection.

**HOW SUPPLIED**

OSTEOSCAN-HDP is supplied as a lyophilized powder packaged in vials. Each vial contains 2.0 mg oximeotide sodium and 0.18 mg stannous chloride as active ingredients, and 0.36 mg gentisic acid as a stabilizer, 1 ml containing 5 or 30 vials are available. The NDC number for this product is NDC: 37000-403-01. The drug can be stored at room temperature both prior to and following reconstitution with ADDITIVE-FREE sodium pertechnetate Tc99m.

For additional product information, call (213) 377-1557 or write: Procter & Gamble, Professional Services, P.O. Box 171, Cincinnati, OH 45201.
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See next page for brief summary.

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NUCLEAR MEDICINE REVIEW SYLLABUS
Peter T. Kirchner, M.D., Editor

The rapid growth of clinical nuclear medicine poses a formidable challenge to the physician who wants to maintain a high level of competence in all areas of nuclear medicine. To help the physician meet this challenge, the Society of Nuclear Medicine has prepared the NUCLEAR MEDICINE REVIEW SYLLABUS, a comprehensive review of the major scientific and clinical advances that have occurred in the Society since the early 1970s.

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- Pulmonary
- Cardiovascular
- Radioassay
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- Skeletal System
- Endocrinology

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Copies are available now at $30.00 each (plus $2.50 per copy for postage and handling). All orders must be prepaid or accompanied by a purchase order. Checks must be in U.S. funds only. Order from: Book Order Dept., Society of Nuclear Medicine, 475 Park Avenue South, New York, NY 10016.

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Ronald R. Price, David L. Gilday, and Barbara Y. Croft, Eds. This volume, which was published in 1980, includes an overview of single photon emission computed tomography and numerous papers that describe and evaluate specific systems and techniques. Papers cover such topics as Anger cameras; seven-pinhole and slant-hole collimators; brain, cardiac, and gated blood-pool studies; and the BICLET and SPECT systems. (SNM members: $18.00 + $2.50 postage and handling; list price $27.00.)

NUCLEAR MEDICINE REVIEW SYLLABUS
Peter T. Kirchner, Ed. This well-indexed volume is a comprehensive review of the major scientific and clinical advances that have occurred in nuclear medicine since the early 1970s. The chapters include Radiopharmacology, Instrumentation, Radiation Effects and Radiation Protection, Cardiovascular, Central Nervous System, Endocrinology, Gastroenterology, Genito-Urinary System, Hematology-Oncology, Pulmonary, Radioassay, and the Skeletal System. ($30.00 + $2.50 postage and handling.)

RADIOPHARMACEUTICALS II:
Proceedings of the 2nd International Symposium on Radiopharmaceuticals
Vincent J. Sodd, David R. Allen, Dennis R. Hoogland, and Rodney D. Ice, Eds. This 809-page volume is a complete compilation of papers from the 1979 International Symposium, including a keynote address by former AEC Chairperson Dixy Lee Ray and a panel discussion entitled “International Regulatory Affairs Relating to Radiopharmaceuticals.” Chapters cover such topics as quality control, organic and inorganic radiopharmaceuticals, functional imaging, RIA, pharmacokinetics, and various body systems. ($40.00 + $2.50 postage and handling. Special Offer! Buy Radiopharmaceuticals II for $40.00 and get Radiopharmaceuticals for only $10.00 + $2.50 each postage and handling.) $7.50 additional for all foreign orders.

Other books available from the Society are: The Heritage of Nuclear Medicine ($14.50); Nuclear Cardiology: Selected Computer Aspects ($12.50); Nuclear Medicine in Clinical Pediatrics ($22.50); Semiconductor Detectors in the Future of Nuclear Medicine ($7.50); Tomographic Imaging in Nuclear Medicine ($12.00); and the Nuclear Medicine Science Syllabus ($30.00).

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MPI Thallous Chloride TI 201 Injection
Thallous Chloride TI 201
Diagnostic — For Intravenous Use
For Imaging Myocardial Perfusion

DESCRIPTION
MPI Thallous Chloride TI 201, Thallous Chloride TI 201, is supplied in isotonic solution as a sterile, nonpyrogenic diagnostic radiopharmaceutical for intravenous administration. Each ml contains 1 mCi Thallous Chloride TI 201 at calibration time made isotonic with 9 mg sodium chloride and preserved with 0.9% (v/v) benzyl alcohol. The pH is adjusted to between 4.5-7.0 with hydrochloric acid and or sodium hydroxide. Thallium TI 201 is cyclotron produced. It is essentially carrier-free and contains no more than 1% TI 200 and no more than 1% TI 202.

CONTRAINDICATIONS
None known

WARNINGS
When studying patients suspected or known to have myocardial infarction or ischemia, care should be taken to assure continuous clinical monitoring and treatment in accordance with safe, accepted procedure. Exercise stress testing should be performed only under the supervision of a qualified physician and in a laboratory equipped with appropriate resuscitation and support apparatus.

Pregnancy Category C

Adequate reproduction studies have not been performed in animals to determine whether this drug affects fertility in males or females, has teratogenic potential, or has other adverse effects on the fetus. Thallous Chloride TI 201 should not be used in pregnant women except when benefits clearly outweigh the potential risks.

PRECAUTIONS
Ideally examinations using radiopharmaceutical drug products—especially those elective in nature—are initiated by women of childbearing capability should be performed during the first ten days following the onset of menses.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, as a general rule nursing should not be undertaken when a patient is administered radioactive material.

Safety and effectiveness in children have not been established.

Carcinogenesis

No long-term animal studies have been performed to evaluate carcinogenic potential.

Data are not available concerning the effect of the quality of Thallium TI 201 scans of marked alterations in blood glucose, insulin or pH (such as is found in diabetes mellitus). Attention is directed to the fact that thallium is a potassium analog, and since the transport of potassium is affected by these factors, the possibility exists that the thallium may likewise be affected.

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

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

This drug should not be used six (6) days after the calibration date.

ADVERSE REACTIONS
Adverse reactions related to use of this agent have not been reported to date.

HOW SUPPLIED
MPI Thallous Chloride TI 201, Thallous Chloride TI 201 is available in 2.0 mCi vials.

medi+physics™

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PLEASE SEE FOLLOWING PAGE FOR BRIEF SUMMARY OF PRESCRIBING INFORMATION.
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*AccuSync-II
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*AccuSync-III
All AccuSync-I features with the exception of the Strip Chart Recorder.

*AccuSync-IV
All AccuSync-III features with the exception of the Heart Rate/R-R int. display.
Diagnosis: normal ventilation, abnormal perfusion — pulmonary embolism

Imaging information:
- Instrument: Picker Model 4/15 Gamma Camera
- Dose: 15 mCi Xenon 133; 3 mCi PULMOLITE
- Information density: 1,000 counts/cm², 2,000 counts/cm²

Xenon Xe 133 Gas (CALIDOSE®) Dispensing System
PULMOLITE™
Technetium Tc 99m Aggregated Albumin Kit

New England Nuclear®

Please see following page for brief prescribing information.
Xenon Xe 133 Gas (CALIDOSE®) Dispensing System

INDICATIONS: Inhalation of xenon Xe 133 gas has proved valuable for the evaluation of pulmonary function and for imaging the lungs. It may also be applied to assessment of cerebral flow.

CONTRAINDICATIONS: To date, no known contraindications to the use of xenon Xe 133 gas have been reported.

WARNINGS: This radiopharmaceutical should not be administered to pregnant or lactating women unless the benefits to be gained outweigh the potential hazards.

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 the menses.

Radiopharmaceuticals should be used only by physicians who are qualified by specific training in the safe use and handling of radionuclides produced by nuclear reactions or particle accelerators, and whose experience and training have been approved by the appropriate governmental agency authorized to license the use of radionuclides.

PRECAUTIONS: As in the use of any other radioactive material care should be taken to insure minimum radiation exposure to the patient, consistent with proper patient management, and to insure minimum radiation exposure to occupational workers. Expired xenon Xe 133 gas should be controlled in a manner that is in compliance with the appropriate governmental agency regulations.

Xenon Xe 133 adheres to some plastics and rubber and should not be allowed to stand in tubing or respirator containers. Such unrecognized loss of radioactivity from the dose for administration may render the study nondiagnostic. Xenon Xe 133 gas delivery systems, i.e., respirator or spiroimeters, and associated tubing assemblies must be leakproof to avoid loss of radioactivity into the laboratory environs not specifically protected by exhaust systems.

ADVERSE REACTIONS: To date, no adverse reactions based on the use of xenon Xe 133 gas have been reported.

DOSAGE AND ADMINISTRATION: Xenon Xe 133 gas is administered by inhalation from closed respirator systems or spiroimeters. The suggested activity range employed for inhalation by the average adult patient (70kg) is:

- Pulmonary function including imaging: 2–30 mCi in 3 liters of air.
- Cerebral blood flow: 10–30 mCi in 3 liters of air.
- The patient dose should be measured by a suitable radioactivity calibration system immediately prior to administration.

HOW SUPPLIED: The xenon Xe 133 gas is supplied as part of the Calidose® system, consisting of 2 ml unit dose vials and the Calidose dispenser® for shielded dispensing.

Normally vials containing either 10 or 20 mCi/vial, packed up to 5 vials per shield tube, are supplied. Vial sets containing up to 100 mCi/vial are available.

PULMOLITE®

Technetium Tc 99m Aggregated Albumin Kit

INDICATIONS AND USAGE: Technetium Tc 99m aggregated albumin is indicated as a lung imaging agent to be used as an adjunct in the evaluation of pulmonary perfusion.

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

The use of 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. This radiopharmaceutical preparation should not be administered to children or to pregnant or lactating women unless the expected benefits to be gained outweigh the potential risks.

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.

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

The content of the kit are not radioactive. However, the sodium pertechnetate Tc 99m is added, adequate shielding of the final preparation must be maintained.

The labeling reactions involved in preparing the agent depend on maintaining tin in the reduced state. Any oxidant present in the sodium pertechnetate Tc 99m supply may thus adversely affect the quality of the prepared agent. Hence, sodium pertechnetate Tc 99m containing oxidants, or other additives, should not be employed without first demonstrating that it is without adverse effect on the properties of the resulting agent.

The contents of the vial are sterile and non-pyrogenic. It is essential that the user follow the directions carefully and adhere to strict aseptic procedures during preparation of the radiodiagnostic.

Technetium Tc 99m aggregated albumin is physically unstable and as such the particles will settle with time. Failure to mix the vial contents 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 aggregated albumin not be used after eight hours from the time of reconstitution. Reconstitute at 2 to 8°C after reconstitution. If blood is withdrawn into the syringe, unnecessary delay prior to injection may result in clot formation in situ.

The contents of the vial are under a nitrogen atmosphere and should be protected from air. Do not use if clumping or foaming of the contents is observed.

Adequate reproduction studies have not been performed in animals to determine whether this drug affects fertility in males or females, has teratogenic potential, or has other adverse effects on the fetus. Technetium Tc 99m aggregated albumin should be used in pregnant women only when clearly needed.

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

Safety and effectiveness in children have not been established.

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

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 governmental 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 more common with radiopharmaceuticals containing proteins or protein-containing materials such as Tc 99m-labeled aggregated albumin is used in man. Epinephrine, antihistamines and corticosteroid agents should be available for use.

DOSAGE AND ADMINISTRATION: The recommended intravenous dose range is for the average patient (70kg) is 1 to 4 millicuries. 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 200,000–700,000 with the suggested number being approximately 350,000.

For easy 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 (U.S.P.).

HOW SUPPLIED: PULMOLITE™ Technetium Tc 99m Aggregated Albumin Kit is supplied in kits of five (5) or thirty (30) vials, sterile and non-pyrogenic, each vial containing in lyophilized form:

- Aggregated albumin (human)-1.0mg
- Normal human serum albumin-10mg
- Sodium chloride-10mg
- Stannous chloride dihydrate, maximum-0.07mg

Each vial contains 3.6–6.5 x 10⁹ aggregated albumin particles.

PULMOLITE contains no preservative; after reconstitution the shielded vial should be stored at 2 to 8°C.

Included in each five (5) vial kit is one (1) package insert and six (6) radiolabels. Included in each thirty (30) vial kit is one (1) package insert and thirty-six (36) radiation labels.

This reagent kit is approved for use by persons licensed by the U.S. Nuclear Regulatory Commission pursuant to Section 35.14 and 35.100 Group III of 10 CFR 35 or under licenses of Agreement States.

Catalog Number NRP-127 * Patent Pending *J0 127 July 1975. Rev 1

Catalog Number NRP-415

August 1976
Bone

Diagnosis: hypertrophic pulmonary osteoarthropathy

Imaging information:
Instrument: GE MaxiCamera™ 535
Dose: 20 mCi OSTEOLITE
Scan time: 2.5-3.0 hours postinjection
Acquisition time: 6 minutes/view

OSTEOLITE™
Technetium Tc 99m Medronate Sodium Kit (MDP)

New England Nuclear®

Please see following page for brief prescribing information.
OSTEOLITE
Technetium Tc 99m Medronate Sodium Kit (MOP)

INDICATIONS AND USAGE: Technetium Tc 99m OSTEOLITE may be used as a bone imaging agent to delineate areas of altered osteogenesis.

CONTRAINDICATIONS: None known.

WARNINGS: The contents of the OSTEOLITE vial are intended only for use in the preparation of Technetium Tc 99m medronate and are NOT to be directly administered to the patient.

Ideally, examinations using radiopharmaceuticals — especially those elective in nature — of women of childbearing capability should be performed during the first ten days following the onset of menses.

POTENTIAL PROBLEMS: A thorough knowledge of the normal distribution of intravenously administered Technetium Tc 99m medronate is essential in order to accurately interpret pathologic studies.

Technetium Tc 99m medronate sodium, as well as any radioactive agent, must be handled with care. Once sodium pertechnetate Tc 99m is added to the kit, appropriate safety measures should be used to minimize external radiation exposure to clinical personnel. Care should also be taken to minimize radiation exposure to patients in a manner consistent with proper patient management.

The use of bacteriostatic sodium chloride as a diluent for sodium pertechnetate Tc 99m may adversely affect the biologic distribution of the prepared agent, and therefore its use is not recommended.

No long-term animal studies have been performed to evaluate carcinogenic potential.

Adverse reproduction studies have not been performed in animals to determine whether this drug affects fertility or teratogenic potential, or has other adverse effects on the fetus. Technetium Tc 99m medronate sodium should be used in pregnant women only when clearly needed. It is not known whether this drug is excreted in human milk. As a general rule, nursing should not be undertaken when a patient is administered radioactive material.

Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: None noted.

DOSAGE AND ADMINISTRATION: The recommended dose for the average 70kg adult patient is 15mCi with a range of 10-20mCi. The patient dose should be measured by a suitable radioactivity calibration system immediately prior to administration.

Optimal imaging results are obtained within one to four hours after administration.

OSTEOLITE should be used within six hours after isotope reconstitution with sodium pertechnetate Tc 99m. For optimum results this time should be minimized.

The vial contains no bacteriostat.

Radiopharmaceuticals should be used by persons who are qualified by specific training in the safe use and handling of radionuclides produced by nuclear reactor or particle accelerator and whose experience and training have been approved by the appropriate governmental agencies authorized to license the use of radionuclides.

HOW SUPPLIED: NEN’S OSTEOLITE™ Technetium Tc 99m Medronate Sodium Kit is supplied as a set of five or thirty vials, sterile and non-pyrogenic. Each nitrogen-flushed vial contains in hypolized form:

Medronate Disodium — 10mg
Stannous Chloride Hydrate — 0.85mg
The pH is adjusted to between 7.0-7.5 with hydrochloric acid and/or sodium hydroxide solution. The contents of the vial were hypoallized under nitrogen.

Store at room temperature (15°-30°C). Included in each five (5) vial kit is one (1) package insert and six (6) radiation labels. Included in each thirty (30) vial kit is one (1) package insert and thirty-six (36) radiation labels.

The contents of the kit vials are not radioactive; however, after reconstitution with sodium pertechnetate Tc 99m the contents are radioactive and adequate shielding and handling precautions must be maintained.

Do not use if there is a vacuum in the liquid medication vial container or if air is injected into the container when the dose is withdrawn.

Catalog Number NRP-420 (5 vial kit)
Catalog Number NRP-420C (30 vial kit)

April 1978

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THE JOURNAL OF NUCLEAR MEDICINE
Diagnosis: arteriovenous malformation

Imaging information:
- Instrument: Ohio Nuclear Series 100 Gamma Camera
- Scan time: 90 minutes postinjection
- Counts: 400 K

Dose: 15 mCi GLUCOSCAN

GLUCOSCAN™
Technetium Tc 99m Gluceptate Sodium Kit

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Rosalyn S. Yalon

A scintillator—a substance that glows from radiation—since they emit particles so weak that they cannot even penetrate a sheet of paper. The volume was enormous, with 500 gal-
lon's annually, accounting for almost half the total waste at the nuclear plant. The Nuclear Regulatory Commission revised its regulations to permit is what it sees as greater leeway in disposal of liquid scintillation waste, another area where it has been accused of overregulation.

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**NRC Has Revised Nuclear Waste Disposal Regulations**

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**Vanderbilt Hosts Its First Nuclear Magnetic Resonance Symposium, Drawing More than 300 Participants**

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**Low-Level Waste Law Should Ease Disposal Problems for Nuclear Medicine**

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**Fear of Radiation**

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AN-MDP is made from medronate and that means low soft-tissue uptake and readily demonstrated bone pathology. With only 4% to 10% remaining in circulation after two hours, time between injection and imaging is conveniently short.

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Sylmar, California 91342
213/365-0655—Inside California
800/423-5620—TOLL FREE Outside California


Please refer to the brief prescribing information on the following page.
AN-MDP® (Technetium Tc 99m Medronate Kit)

For complete prescribing information, consult the package insert, a summary of which follows.

INDICATIONS AND USAGE. Technetium Tc 99m Medronate may be used as a bone imaging agent to delineate areas of altered osteogenesis.

CONTRAINDICATIONS. None known.

WARNINGS. This class of compounds is known to complex cations such as calcium. Particular caution should be used with patients who have, or may be predisposed to hypercalcemia (i.e., alkalosis).

PRECAUTIONS. Contents of the vial are intended only for use in the preparation of Technetium Tc 99m Medronate and are NOT to be administered directly to the patient. Technetium Tc 99m Medronate, as well as other radioactive drugs, must be handled with care, and appropriate safety measures should be used to minimize radiation exposure to the patient consistent with proper patient management.

To minimize radiation dose to the bladder, the patients should be encouraged to drink fluids and to void immediately before the examination and as often thereafter as possible for the next 4–6 hours.

Technetium Tc 99m Medronate should be formulated within six (6) hours prior to clinical use. Optimal imaging results are obtained 1–4 hours after administration. Carcinogenesis, Mutagenesis, Impairment of Fertility: No long-term animal studies have been performed to evaluate carcinogenic potential or whether Technetium Tc 99m Medronate affects fertility in males and females.

Pregnancy Category C: Animal reproductive studies have not been conducted on Technetium Tc 99m Medronate. It is also not known whether Technetium Tc 99m Medronate can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Technetium Tc 99m Medronate should be given to a pregnant woman only if clearly needed. Ideally, examinations using radiopharmaceuticals, especially those electively 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 Medronate is excreted in human milk during lactation; therefore, formula feedings should be substituted for breast feedings.

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 radiomolecules and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides.

ADVERSE REACTIONS. No adverse reactions specifically attributable to the use of Technetium Tc 99m Medronate have been reported.

DOSEAGE AND ADMINISTRATION. The suggested dose range for i.v. administration, after reconstitution with either diluent free sodium perchlorate Tc 99m injection, to be employed in the average patient (70 Kg) is:

Bone imaging: 10–20 millicuries Technetium Tc 99m Medronate. Scanning is optimal at 1–4 hours post-injection. The patient dose should be measured by a suitable radiotracer calibration system immediately prior to administration.

HOW SUPPLIED. The AN-MDP® Technetium Tc 99m Medronate Kit is supplied either as a set of 5 or 30 sterile and pyrogen-free vials. Each nitrogen-flushed vial contains in lyophilized form: medronic acid 10 mg, stannous chloride (minimum) 0.51 mg, maximum total stannous and stannic chloride 1.01 mg. The pH is adjusted with HCl or NaOH solutions prior to lyophilization. Included in each 5-vial kit is one package insert and 10 radiation labels. Included in each 30-vial pack is one package insert and 60 radiation labels. Refrigeration is not necessary. Technetium Tc 99m Medronate Kits contain no preservatives. Vials are sealed under nitrogen: air or oxygen is harmful to the contents of the vials and the vials should not be vented.

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<th>DESCRIPTION</th>
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<td>30-vial ECONO-PAK</td>
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60A THE JOURNAL OF NUCLEAR MEDICINE
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