



# Sodium Iodide I 123

■ Radioiodine is trapped by the thyroid and organified in the synthesis of thyroxine. <sup>99m</sup>TcO<sub>4</sub><sup>-</sup> is also trapped by the thyroid but is not organified. Consequently, Tc99m activity does not always indicate the physiologic condition of the thyroid.<sup>1</sup>

Radioiodine clearly demonstrates the "cold," non-functioning nodules that may be associated with malignant thyroid tumors. Such nonfunctioning nodules have appeared "hot" or "cold" on images obtained with Tc99m, necessitating a confirmatory radioiodine scan.<sup>2,3</sup>

3 Radioiodine thyroid imaging is preferred to Tc99m in such instances as investigation of patients with possible retrosternal thyroid tissue or with unsatisfactory Tc99m images due to poor radionuclide concentration.<sup>3</sup>

Steinbach, HL, Kundy, D, Moss, M, et al. A comparison of three agents in thyroid uptake and scintigraphy. Scientific Exhibit, Society of Nuclear Medicine, Philadelphia, June 16-20, 1975.

\*Information for Physicians—Irradiation-Related Thyroid Cancer" prepared by the Division of Cancer Control and Rehabilitation, National Cancer Institute, DHEW Publication No. (NIH) 77-1120, p.13.

\*Arnold, JE, Pinsky, S: Comparison of \*\*\*\* Tc and \*\*\* I for Thyroid Imaging. J. Nucl. Med., 17:261,1976.

# Organification is Imperative to Thyroid Studies



A palpable nodule in the left lower lobe present for at least six years considered to be "functioning" on the 99m TcO, - image.

Medi-Physics Sodium Iodide I 123 is important for informative thyroid studies. The principle gamma emission of I 123 is 159 keV which is well suited for gamma camera imaging. The 13.2 hours half-life and lack of non-penetrating radiations minimize the absorbed radiation dose. Thyroid uptake studies may be performed at 2, 4, 6, and



The <sup>123</sup>I image demonstrated that this nodule was "non-functioning.

24 hours. If desired, a thyroid scan and a quantitative radioiodine uptake measurement may be performed simultaneously. Sodium lodide I 123 is available in capsules or solution for next day delivery almost anywhere in the United States. Call Toll Free (in Calif.) (800) 772-2446; (outside Calif.) (800) 227-0483 for further information.

# medi+physics

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

#### **SODIUM IODIDE | 123**

#### CAPSULES AND SOLUTION FOR ORAL ADMINISTRATION

**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 solution with 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 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 123 would be preferable to the use of 1131 in order to mini-mize radiation dosage.

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

increase of radionuclidic contaminants with time. The uptake of 1 123 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 re-ported in a series of 1,393 administrations. None of these were attributed to 1 123. 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. **DOSAGE AND ADMINISTRATION:** The recommended oral dose

DOSAGE 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

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 1 123 for oral administration is supplied in aqueous solution in glass vials and in capsules.

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### Technetium Tc 99m Medronate Kit

### BRIEF SUMMARY OF PRESCRIBING INFORMATION

### 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 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).

This radiopharmaceutical drug product should not be administered to children, to pregnant women, or to nursing mothers, unless the expected benefit to be gained outweighs the potential risk.

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

#### general

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 clinical personnel. Also, care should be taken to minimize radiation exposure to the patients consistent with proper patient management.

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

This preparation contains no bacteriostatic preservative. Technetium Tc 99m Medronate should be formulated within six (6) hours prior to clinical use.

### pregnancy category C

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. Technetium Tc 99m Medronate should be used in pregnant women only when clearly needed.

KIT

### 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

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

### how supplied

Union Carbide's Technetium Tc 99m Medronate Kit is supplied as a sterile, pyrogen-free kit containing 5 vials.

Each 10 ml vial contains 10 mg medronic acid, 0.17 mg (minimum) stannous chloride (maximum stannous and stannic chloride 0.29 mg), and 2 mg ascorbic acid. The pH has been adjusted to 4-8 with either HCl or NaOH prior to lyophilization. Following lyophilization, the vials are sealed under a nitrogen atmosphere.

Product #17500502 Multidose vial shield with cap and retainer ring available separately.



Manufactured For:

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# e new erator



# *echnetium* **Ic 99m**

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Model Number	Application	Number of Simultaneous Image Planes	Geometric Resolution (x, y, z) (mm FWHM)	Average Sensitivity Per Image Plane*	Maximum Useable System Count Rate**
4500	Body	7	10.0	16000	106
4600	Neuro	9	8.5	29000	5 x 10 <sup>5</sup>
4650	Neuro	7	5.5	16000	3.8 x 10 <sup>5</sup>

\*Sensitivity expressed as counts/sec per µCi/cm³ for activity uniformly dispersed in 20 cm diameter, water-filled vessel.

\*\*Defined as the "Trues" rate (counts/sec) at which true counts and random counts are equally abundant in the raw data prior to correction and image reconstruction. Tests conducted with 20 cm diameter water-filled phantom extending well beyond detector shield.



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**Top** – Subdural hematoma on left, seen in 76-year-old male with 20 mCi D.T.P.A. **Bottom** – Anterior chest of a 76-year-old male with 15 mCi Tc<sup>99m</sup> P.Y.P.; slight rotation gives a three dimensional effect.







Above - The UNION CARBIDE Hand-held Console.



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**Below** – Organ mode Gallium scans of a 30 year old male 72 hours post-injection (posterior and anterior views) and 96 hours post-injection with 5 mCi of Ga-67. Abnormal activity in the lower abdomen is seen clearly with two photo peaks.







**Above** – Actual 13.5 to 1 minification of posterior and anterior whole body bone scan of a 45 year old male two hours post-injection with 20 mCi Technetium Tc<sup>99m</sup> MDP. Diagnosis: normal.



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### Technetium Tc 99m Normal Serum Albumin (Human) Reagent Kit DIAGNOSTIC-FOR INTRAVENOUS USE

#### BRIEF SUMMARY OF PRESCRIBING INFORMATION

#### indications and usage

Technetium Tc 99m Human Serum Albumin is used as an agent for imaging the heart blood pool and to assist in the detection of pericardial effusion and ventricular aneurysm.

#### contraindications

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

#### warnings

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.

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

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

#### 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 radiodiagnostic.

Technetium Tc 99m Human Serum Albumin must not be used after three hours from the time of formulation.

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 Human Serum 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.

Technetium Tc 99m Human Serum Albumin, 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.

The labeling reactions involved in preparing the agent depend on maintaining the 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.

#### adverse reactions

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

#### how supplied

#### unit dose kit

The kit consists of 10 unit dose reaction vials each containing a lyophilized mixture of 7 mg human serum albumin and 0.08 mg stannous tartrate. Hydrochloric acid was added prior to lyophilization for pH adjustment.

#### multidose kit

The kit consists of 5 multidose reaction vials each containing a lyophilized mixture of 21 mg human serum albumin and 0.23 mg stannous tartrate. Hydrochloric acid was added prior to lyophilization for pH adjustment.

### FOR FULL PREPARATION AND PRESCRIBING INFORMATION, SEE PACKAGE INSERTS.

Notes: 'Refer to package insert for full preparation and prescribing information. <sup>2</sup>Data on file at Union Carbide Corporation, Tuxedo, New York



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### High speed, high resolution, high efficiency. Therascan 3128 Positron Emission Tomograph from AECL.



Therascan 3128 from Atomic Energy of Canada Limited is the first bismuth germanate ring system in routine clinical use for both outpatient and inpatient studies. A state-of-the-art emission tomograph, it establishes new frontiers in neurological diagnosis and research investigations. Versatile and simple to operate, requiring little computer expertise, the Therascan 3128 method provides a safe, rapid, three-dimensional measurement of brain blood flow as well as biochemical mapping of the brain. Its role is especially significant for patients suffering from strokes, epilepsy, brain tumour, dementia, or other metabolic disorder.

The clinical example shown above demonstrates the unique ability of Therascan to perform dynamic studies of regional cerebral blood flow for diagnosis and treatment evaluation. Pictured is a comparison of pre-op and post-op rCBF studies. The patient had experienced dysphasia with mild paralysis in the right extremities. Clinical signs indicated ischemia in the left fronto-parietal area. An angiogram showed complete occlusion of the left internal carotid artery and a 30% stenosis of the right internal carotid artery, while a CT scan showed no abnormality. However, Therascan 3128, using the isotope "Kr,

showed a marked reduction of cerebral blood flow in a large portion of the left fronto-central area, the right parietal area, and the right anterior frontal area. The patient subsequently underwent extra-intracranial arterial anastomosis (bypass surgery), and the general improvement at the three month follow-up is shown very clearly in the scan on the right.

The extraordinary efficiency of the detector array allows Therascan to image three slices simultaneously in as little as one second, creating many new possibilities for investigations of rapidly changing phenomena. Therascan achieves superior quality scans for both dynamic and static studies, using

generator produced isotopes like <sup>66</sup>Ga, and the shortlived isotopes <sup>11</sup>C, <sup>13</sup>N, <sup>15</sup>O and <sup>18</sup>F, as produced by the JSW Mini Cyclotron (also from AECL.)

Therascan 3128 is truly a radical departure, a major advance, in nuclear medicine. To discover its exceptional versatility and unparalleled detection efficiency firsthand, contact AECL.



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The JSW Mini Cyclotron from Atomic Energy of Canada Limited dramatically expands the capabilities of diagnostic nuclear medicine. A radical departure from traditional accelerator technology, it is the first cyclotron available dedicated to the clinical environment, offering hospitals and research institutions a variety of immediate advantages. Its role significance is especially evident when viewed in the light of recent major developments in new imaging systems specifically, positron emission cameras such as AECL's Therascan 3128. The Mini Cyclotron allows these new physiological tomography systems to achieve full operation potential by making the crucial, short half-life radioisotopes 11C, 13N, 15O, and 18F immediately available within the nuclear medicine department.

Compact, the Mini Cyclotron can be installed in an area of only 20 square meters. Economic, it features both proton and deuteron acceleration, eliminating the need for expensive, enriched target gases. Safe, simple, reliable, little training is required for its operation, while an innovative two-part design ensures swift, easy servicing. Nuclear medicine comes of age with the JSW Mini Cyclotron. And it's available now! For complete information, contact AECL.



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... has been accompanied by a noticeable improvement in the guality and consistency of the scans compared to the previously used HEDP."<sup>1</sup>

"The MDP complex produced images of superior quality as early as two hours after administration, attributable to its more rapid clearance from the blood and soft tissues. On the contrary, a longer interval of 3-4 hours after injection was usually needed for <sup>99m</sup>Tc-EHDP: pyrophosphate and polyphosphate complexes regularly required a waiting period of four hours."<sup>2</sup>



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Please refer to brief summary on next page

### **Introducing Mallinckrodt TechneScan<sup>®</sup> MDP Kit** (Technetium Tc99m Medronate Sodium) The latest advance in skeletal imaging.



#### **References**:

Davis MA, Jones AG: Comparison of <sup>sem</sup>Tc-Labeled Phosphate and Phosphonate Agents for Skeletal Imaging. Sem. Nucl. Med. 6:19, 1976.
 Subramanian G, McAfee JG, Blair RJ, et al: Technetium-99m-methylene Diphos-phonate—A Superior Agent for Skeletal Imaging: Comparison with Other Technetium Com-plexes. J. Nucl. Med. 16:744, 1975.

### INDICATIONS AND USAGE

Technetium Tc 99m Medronate Sodium 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 elective 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 Sodium 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 Sodium 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 Sodium.

### DOSAGE AND ADMINISTRATION

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

The patient should be encouraged to drink fluids before and after the examination and 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 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**

### TechneScan MDP Kit-Technetium Tc 99m **Medronate Sodium Kit**

Product No. 088

Each kit consists of 5 reaction vials, each vial containing, in lyophilized form, sterile and non-pyrogenic:

Medronic Acid	10 mg
Stannous Chloride	1 mg

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

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

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1. Sem Nucl Med 6:107, 1976





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### Most rapid blood clearance<sup>2</sup>

• At 90 minutes postinjection, blood clearance of MDP pharmacologically identical to OSTEOLITE was approximately equal to that of tested pyrophosphate agents at 6 hours postinjection.

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The "difference in soft tissue activity (highest with polyphosphate and lowest with MDP) is discernible in clinical images."<sup>2</sup> A University of Minnesota study found that only 4% of 175 MDP images showed moderate to marked soft tissue activity, compared to 17% of EHDP images.<sup>3</sup>

Result: highest assurance of visualizing all skeletal structures.

### Highest target-to-background differential<sup>4</sup>

OSTEOLITE's rapid blood clearance and lower soft tissue uptake usually enable current gamma cameras to resolve peripheral skeletal structures and phalanges.

Result: confidence of detecting resolution-challenging alterations in osteogenesis...even roentgenographically "invisible" fractures and small metastases.

### **Convenient storage and preparation**

Available in 5-vial or 30-vial "Convenience Packs," OSTEOLITE can be stored and used at room temperature (15–30 C).

REFERENCES

<sup>1.</sup> Marty R et al: Bone trauma and related benign disease: Assessment by bone scanning. Sem Nucl Med 6:107, 1976

Subramanian G et al: Technetium-99m-methylene diphosphonate—a superior agent for skeletal imaging: Comparison with other technetium complexes. J Nucl Med 16:744, 1975

<sup>3.</sup> Forstrom L et al: Data on file at New England Nuclear, Medical Diagnostics Division, North Billerica, MA

<sup>4.</sup> Davis MA, Jones AG: Comparison of 99m Tc-labeled phosphate and phosphonate agents for skeletal imaging. Sem Nucl Med 6:19, 1976

# Technetium Tc 99m Medronate Sodium Kit (MDP)



RL, right knee



Post



LL, right knee



Ant

A 23-year-old graduate student actively engaged in amateur soccer complained of pain in both knees. X-rays of both knees suggested the possibility of a stress fracture only at the right proximal tibia. **OSTEOLITE** images of the right knee displayed focal uptake in the proximal tibia. consistent with the diagnosis of a stress fracture. A routine anterior view of both knees disclosed a roentgenographically occult stress fracture of the left proximal tibia as well.

Images produced with 19.6 mCi technetium-99m labeled OSTEOLITE; recorded at 500 K counts, Searle LFOV<sup>™</sup> camera with Micro Dot<sup>™</sup> Imager.



## **OSTEOLITE** Technetium Tc 99m Medronate Sodium Kit (Formerly Known as MDP)

DESCRIPTION: New England Nuclear's OSTEOLITE<sup>™</sup> Technetium Tc 99m Medronate Sodium Kit (formerly known as MDP), is supplied sterile and non-pyrogenic in lyophilized kit form suitable for reconstitution with sodium pertechnetate Tc 99m to form a diagnostic skeletal imaging agent for intravenous administration. Each vial contains 10mg medronate disodium and 0.85mg stannous chloride dihydrate; pH is adjusted to between 7.0–7.5 with hydrochloric acid and/or sodium hydroxide solution. The contents of the vial are lyophilized and stored under nitrogen.

#### PHYSICAL CHARACTERISTICS

Technetium Tc 99m decays by isomeric transition with a physical half-life of 6.02 hours. (SOURCE: Martin, M. J. Nuclear Data Project, Oak Ridge National Laboratory, March, 1976.) Photons that are useful for imaging studies are listed in Table 1.

Table 1. Principal Radiation Emission Data— Technetium Tc 99m			
Padiation	Mean %/	Mean Energy (kal/)	
Gamma-2	88.96	140.5	

To facilitate correction for physical decay of Technetium Tc 99m, the fractions of initial activity that remain at selected intervals after the time of calibration are shown in Table 2.

#### Table 2. Physical Decay Chart; Technotium Tc 99m Half-Life 6.02 Hours

Hours	Fraction Remaining	Hours	Fraction Remaining
0*	1.000	8	.398
1	.891	9	.355
2	.794	10	.316
3	.708	11	.282
4	.631	12	.251
5	.562	18	.126
6	.501	24	.063
7	.447		

#### \*Calibration Time

#### EXTERNAL RADIATION

The specific gamma ray constant for Technetium Tc 99m is 0.8R/mCi-hr. at 1cm. The half value layer is 0.2mm of Pb. To facilitate control of radiation exposure from millicurie amounts of Technetium Tc 99m, the use of a 6.35mm thick standard radiation elution lead shield will attenuate the radiation emitted by a factor greater than  $10^{-4}$ .

#### **Table 3. Radiation Attenuation By Lead Shieldin**

Shield Thickness (Pb)mm	Coefficient of Attenuation	
0.2	0.5	
0.95	10-1	
1.8	10-2	
2.7	<b>10</b> -3	
3.6	10 -4	
4.5	10 - 5	
5.4	10 - 6	
6.3	10-7	

**CLINICAL PHARMACOLOGY:** Upon intravenous injection, Technetium Tc 99m OSTEOLITE exhibits a specific affinity for areas of altered osteogenesis. In humans, blood levels fall to 4-10% of the injected dose by two hours post-injection and to 3-5% by three hours. During the first 24 hours following its administration in patients with normal renal function, 50-75% of the radioactivity is excreted into the urine and less than 2% of the injected dose remains in the vascular system.

Uptake of the Technetium Tc 99m in bone appears to be related to osteogenic activity and to skeletal blood perfusion. The deposition in the skeleton is bilaterally symmetrical, with increased accumulation in the axial structure as compared to the appendicular skeleton. There is increased activity in the distal aspect of long bones as compared to the diaphyses. In pediatric patients, in whom the epiphyseal centers are still open, there is more marked accumulation of the radiopharmaceutical in the distal aspects of long bones than is seen in adults in whom the epiphyseal centers are closed. Localized areas of abnormal accumulation of the radiopharmaceutical may be seen in primary skeletal malignancies, metastatic malignancies to bone, acute or chronic osteomyelitis, arthritides, recent fractures, areas of ectopic calcification, Paget's disease, regional migratory osteoporosis, areas of aseptic necrosis and, in general, any pathological situation involving bone in which there is increased osteogenic activity or localized increased osseous blood perfusion. Since increased osteogenic activity and localized increased osseous blood perfusion are not usually present in chronic bone diseases, bone imaging agents, in general, are not effective in detecting such diseases. Localized areas of decreased accumulation of the radiopharmaceutical may be noted in areas of bone which have received localized fields of external radiation or to which blood flow has been interrupted. OSTEOLITE has also been noted to accumulate in areas of acute myocardial infarction from one to fourteen days after the pathologic event.

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 sodium 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.

PRECAUTIONS: A thorough knowledge of the normal distribution of intravenously administered Technetium Tc 99m medronate sodium 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 Technetium Tc 99m labeling reaction involved in preparing Technetium Tc 99m medronate sodium depends on the maintenance of tin in the divalent state. Any oxidant present in the sodium pertechnetate Tc 99m employed may adversely affect the quality of the prepared agent. Thus, sodium pertechnetate Tc 99m containing oxidants should not be used without first demonstrating that it is without adverse effect on the properties of the resulting agent.

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 its use is not recommended.

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 medronate



601 Treble Cove Rd., North Billerica, MA 01862 Call toll-free: 800-225-1572 Telex: 94-0996 (In Massachusetts and International: 617-482-9595)

Los Angeles: NEN West, 17210 South Gramercy Place, Gardena, California 90247 Tel: 213-321-3311 Canada: NEN Canada, 2453 46th Avenue, Lachine, Que. H8T 3C9 Tal: 514-656-4971

Europe: NEN Chemicals GmbH, D-6072 Dreieich, W. Germany, Postfach 401240 Tel: (06103) 85034 Order Entry: (06103) 81013 October 1977

sodium should be used in pregnant women only when clearly needed.  $\hfill \hfill \hfi$ 

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.

**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 aseptic 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.

#### RADIATION DOSIMETRY

The estimated absorbed radiation dose to an average patient (70kg) from an intravenous injection of a maximum dose of 20 millicuries of Technetium Tc 99m OSTEOLITE is shown in Table 4.

#### **Table 4. Absorbed Radiation Dose**

Technet	tium Tc 99m Medro	nate Sodium
Organ		(rads/20mCi)
Total Body		0.13
Bone Total		0.70
Red Marrow		0.56
Kidneys		0.62
Liver		0.16
Bladder Wall	2 hr void	2.60
	4.8 hr void	6.20
Ovaries	2 hr void	0.24
	4.8 hr void	0.34
Testes	2 hr void	0.16
	4.8 hr void	0.22

Method of calculation: A Schema for Absorbed-Dose Calculations For Biologically Distributed Radionuclides, Supplement No. 1, MIRD Pamphlet No. 1, p. 7, 1968.

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 lyophilized form:

Medronate Disodium-10mg

Stannous Chloride Dihydrate-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 lyophilized 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.

INSTRUCTIONS FOR PREPARATION OF TECHNETIUM To 99m OSTEOLITE: Aseptically inject 2 to 8ml of sodium pertechnetate To 99m (pertechnetate in isotonic saline without a bacteriostat) into the supplied vial of OSTEOLITE enclosed by a radiation shield. Swirl for at least ten seconds to dissolve completely. Label appropriately. Suitable labels have been supplied with each OSTEOLITE Kit. Use within six hours after reconsti-

tution. For optimum results, this time should be minimized. Using proper shielding, the vial containing the reconstituted solution should be visually inspected to insure that it is clear and free of particulate matter.

#### 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 immediate drug 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)

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- WITTING OF BUILDING TO THE CONTRACTION OF STATES OF STAT - constant plane thicknesses with automatic correction for pinhole magnification.
- a complete system, including a collimator, and everything needed for 7-pinhole tomography.
- economy and simplicity, by utilizing your existing camera and computer system.

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. . . . In a word, 7-pinhole tomography is a breakthrough;

> **GAMMECAT** is its most advanced application available.



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Vogel RA, Kirch DL, Lefree MT, Rainwater JO, Steele PP: Thallium-201 myocardial perfusion scintigraphy: Results of standard and multi-pinhole tomographic techniques. The American Journal of Cardiology 43:787-793, 1979

<sup>2</sup>Francisco D, Raymundo G, Van Kirk O, Erhardt J. Marcus M: Tomographic thallium-201 perfusion scintigrams following maximal coronary vasodilation with dipyridamole: Circulation (in press) "DEC Gamma 11 is a trademark of Digital Equipment Corporation

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SCOPIX CR3 Film The one film that does it all!

Photos courtesy Mt. Sinai Hospital, N.Y.

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4

11

## WHEN YOU DO SOMETHING



November 8, 1895. Wilhelm Roentgen discovered a "new kind of light" that he called x-rays, and quickly made the first radiograph of a human subject —his wife's hand.



Physicians discovered photography early, and used photos for teaching and record keeping. They were among Kodak's first customers. (1845-1923) Wilhelm Konrad Roentgen

An early Kodak darkroom lamp was a candle in a red fabric box. Today's Kodak safelight filter type GBX is "universal" and safe with all blue- and most greensensitive x-ray films.

The first Kodak "demonstrator" was hired in 1884. Today, technical sales representatives call on the medical profession to provide imaging expertise and backup.

## FOR A VERY LONG TIME...





Nuclear medicine



Computed tomography



Ultrasound

CRT color photography

As the new imaging modalities required new products, Kodak responded. If there is an image to be recorded, there is a Kodak film on which to record it.

© Eastman Kodak Company, 1979

Eastman Kodak Company, founded in 1880, occupied this plant in Rochester, New York. Kodak headquarters now occupy the site.



Kodak Lanex screens and Kodak ortho films provide quality images with benefits ranging from exposure reduction to increased technic flexibility.



## YOU GET TO BE

From the beginning, Kodak provided chemicals for processing, and even sold the balances for measuring them. Today, the Kodak automixer delivers fresh chemicals to

G film OC

nat RP film

processors, relieving department person-

nel of a time-consuming chore.

Infinition



Kodak first prepackaged dental x-ray film in 1913.



Kodak X-Omatic cassette, introduced in 1971. Curved panel design forces out trapped air and provides intimate screen/film contact.

#### Kodak had film before Roentgen had the ray,

establishing a tradition of meeting the needs of medical imaging. No other company catalogs as many films as Kodak.

XL-1

XRP-1

XR-1

VS-1

SB-5

## **VERY GOOD AT IT.**

Imaging is not complete without proper processing. An early Kodak advertisement showed a Kodak film processor that operated by the turn of a crank.





Today, the Kodak RP X-Omat processor, model M8, processes x-ray film in 90 seconds and monitors its own performance automatically.



Kodak's 100-year commitment to its customers has always included instruction on the use of its products. Many courses are conducted at the Kodak Marketing Education Center.



Kodak publications. X-ray Bulletin began in 1925; became Medical Radiography and Photography in 1947.

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George Eastman, 1854-1932. He started it all.

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100 YEARS OF TURNING ENERGY INTO IMAGES



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**CINTICHEM® TECHNETIUM 99m MAA UNIT DOSE** and **MULTIDOSE** both offer the following advantages:

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• **STABLE FORMULATION** – Prepared with Stannous Tartrate<sup>2</sup>, which is more resistant to oxidation than Stannous Chloride.

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- UNIT DOSE kits each contain 10 vials
- UNIT DOSE kits are competitively priced with 5 vial multidose kits
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- UNIT DOSE kits can reduce your average cost per dose if an average of one perfusion study is routinely performed per day; ideal for low volume departments

**CINTICHEM® TECHNETIUM 99m MAA MULTIDOSE**, for use with up to 90 mCi per vial, can provide moderate to high patient volume departments with the optimum economical dosage availability from a single vial.

<sup>1</sup> See Union Carbide CintiChem<sup>®</sup> Technetium 99m MAA Unit Dose or Multidose package insert for full preparation instructions.

<sup>2</sup> Union Carbide Reg. U.S. Patent Office # 3987157

<sup>3</sup> Refer to Union Carbide and competitive package inserts for full lung dosimetry information.

## TO ORDER OR FOR ADDITIONAL INFORMATION

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IN N.Y.S. CALL (914) 351-2131 EXT 227

You can also take advantage of the other **CINTICHEM® ECONOMIC ALTERNA-TIVES** by ordering today Unit Dose and/or Multidose **Technetium 99m DTPA** (DTPA Tin Kit For Use In The Preparation of Technetium Tc 99m DTPA Tin Chelate) and **Technetium 99m HSA** (Technetium Tc 99m Serum Albumin (Human) Reagent Kit).

THE ECONOMIC ALTERNATIVES such as CINTICHEM® TECHNETIUM 99m MAA UNIT DOSE and MULTIDOSE (Technetium Tc 99m Aggregated Albumin Kit), can be utilized to maximum economic advantage by preparation of the vial size that best meets your daily scheduling and immediate dosage needs.

With a **CINTICHEM® STANDING ORDER** (the original "convenience packaging") you can mix your purchase and delivery of CintiChem<sup>®</sup> 10 vial UNIT DOSE and 5 vial MULTI DOSE kits at the same competitive price.

Compared to competitive "convenience packaging", a CintiChem<sup>®</sup> Standing Order allows you to optimize your kit purchases and delivery schedule to meet your individual dosage needs; reduces your shelf space requirements; and continuously assures you of product with the longest expiration date available.

### **CINTICHEM**<sup>\*</sup>

TECHNETIUM 99M

**MAA** Technetium Tc 99m Aggregated Albumin Kit

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## CintiChem

## MAA Technetium Tc 99m MAA Aggregated Albumin Kit

## BY ALL INDICATIONS; THE SOLUTION FOR YOUR LUNG IMAGING NEEDS

#### BRIEF SUMMARY OF PRESCRIBING INFORMATION

#### 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 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 any 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, to pregnant women 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 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.

The labeling reactions involved in preparing the agent depend on maintaining the 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 pyrogen-free. It is essential that the user follows the directions carefully and adheres 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 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 Aggregated Albumin not be used after eight hours from the time of preparation. Refrigerate at 2° to 8° C after preparation. 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. On preparation with Sodium Pertechnetate Tc 99m, the contents of the vial should be mixed by gentle swirling to avoid changes in particle size. 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 patient management, and to insure 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 occuring after the administration of aggregated albumin to patients with pre-existing severe pulmonary hypertension. Instances of hemodynamic or idiosyncratic reactions to preparations of Technetium 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 corticosteroid agents should be available for use.

#### how supplied

#### unit dose kit

The kit consists of 10 unit dose reaction vials, each containing 0.11 mg of Aggregated Normal Human Serum Albumin (MAA), 0.09 mg stannous tartrate, and 0.3 ml of isotonic saline. Hydrochloric acid and/or sodium hydroxide may have been added for pH adjustment. Each vial contains 0.5 – 1.0 X 10<sup>6</sup> aggregated albumin particles.

#### multidose kit

The kit consists of 5 multidose reaction vials, each containing 0.34 mg of Aggregated Normal Serum Albumin (Human) MAA 0.27 mg stannous tartrate, and 0.6 ml of isotonic saline. Hydrochloric acid and/or sodium hydroxide may have been added for pH adjustment. Each vial contains 2.0 X 10<sup>6</sup> ±25% aggregated albumin particles.

FOR FULL PREPARATION AND PRESCRIBING INFORMATION, SEE PACKAGE INSERT

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- Audible and visual indicators alert you BEFORE a hazardous xenon concentration is reached.
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<sup>(1)</sup>The Code of Federal Regulations† clearly limits the permissible <sup>133</sup>Xe exposure to 1 MPC for 40 hours per week for 13 weeks. The data is continuously updated and displayed by the "XenAlert." †10 CFR, Part 20, Sec. 20.103 and Appendix B, Table 1.



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If you've been waiting for an economical way to produce high-quality, low-background medronate (MDP) bone images, wait no more. AN-MDPTM, from Ackerman Nuclear, Inc., gives you all of the advantages of medronate-and a lot of medronate for your money. Posterior right side

Now there's an economical agent AN-NIDP<sup>™</sup> Technetium Te 99m Medronate Kit to-background scans that readily demonstrate altered osteogenesis! 90-94% blood clearance by two hours after administration

Lowest soft-tissue uptake of all of the phosphonate bone agents in current use.3

- room temperature (15-30°C).
- You get 6 vials of reagent with Economy each AN-MDP kit, instead of the usual 5.

Posterior pelvis

A 54-year-old male with metastatic CA of the prostate was administered 15 mCi technetium Tc 99m-labeled AN-MDP. The images were recorded at 500K counts. Courtesy of Century City Hospital. Los Angeles. Century City Hospital, Los Angeles.

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

AN-MDP™ Technetium Tc 99m Medronate Kit

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 who may be predisposed to hypocalcemia (i.e., alkalosis)

Precautions. Contents of the vial are intended only for use

e preparation of Technetium Tc 99m Medronate and are In the preparation of technetium ic 99m Medronale 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 patients consistent with proper patient management.

To minimize radiation dose to the bladder, 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 /aluate carcinogenic potential or whether Technetium Tc 99m Medronate affects fertility in males or females.

Pregnancy category C: Animal reproductive studies have not been conducted with 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 reproduction capacity. Technetium Tc 99m 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 humar milk during lactation, therefore formula feedings should be substituted for breast feedings.

CUT WASTE. You can choose either single-dose or multidose vials to match your department's volume. For greater savings, both single-dose and multidose AN-MDP come in 30-vial ECONO-PAKS.

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already enjoy the benefits of "MDP" scans. To place your order today, just call us collect: (213) 240-8555. 1. Davis MA, and Jones AG: Sem Nucl Med 6:19, 1976 2. Subramanian G, McAfee JG, Blair RJ, Kallfelz FA, and Thomas FD: J Nucl Med

16:744, 1975

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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 radionuclides 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.

Dosage and administration. The suggested dose range for i.v. administration, after reconstitution with oxidant-free sodium pertechnetate Tc 99m Injection, to be employed in the numerous existed (70 km) in the average patient (70 kg) is:

Bone imaging: 10-20 mCi Technetium Tc 99m Medronate

Scanning is optimal at about 1–4 hours post-injection. The patient dose should be measured by a suitable radioactivity calibration system immediately prior to administration.

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- Bonadonna, G. et al: Phase I and preliminary Phase II evaluation of adriamycin (NSC 123127), Cancer Res. 30, 2572, 1970
- 2. Middleman, E. et al: Clinical trials with adriamycin. Cancer, 28, 844, 1971
- 3. Wang, J. et al: Therapeutic effect and toxicity of adriamycin in patients with neoplastic diseases. Cancer, 28, 837, 1971

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- 1. S.W. Pitman et al: Clinical Trial of High-Dose Methotrexate (NSC-740). With Citrovorum Factor (NSC-3590)-Toxicologic and Therapeutic Observations. Cancer Chemotherapy Reports Part 3 Vol. 6, No. 1, July 1975.
- 2. Stoller, Ronald G. et al: Use of Plasma Pharmacokinetics to Predict and Prevent Methotrexate Toxicity. N.E. Jr. of Med. Vol. 297 No. 12:630-634, Sept. 22, 1977.
- Jaffe N. and Traggis D. Toxicity of high-dose methotrexate (NSC- 740) and citrovorum factor (NSC-3590) rescue in osteogenic sarcoma. Cancer Chemother. Rep. Part 3, Vol.6(1):31-36, 1975.

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### DIAGNOSTIC ISOTOPES MDP KIT TECHNETIUM Tc 99m MEDRONATE KIT

#### INDICATIONS AND USAGE

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

CONTRAINDICATIONS

#### WARNINGS

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).

This radiopharmaceutical drug product should not be administered to children, to pregnant women, or to nursing mothers, unless the expected benefit to be gained outweighs the potential risk.

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

General

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 clinical personnel. Also, care should be taken to minimize radiation exposure to the patients consistent with proper patient management.

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

This preparation contains no bacteriostatic preservative.

Technetium Tc 99m Medronate should be formulated within six (6) hours prior to clinical use.

#### Pregnancy Category C

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. 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.

#### Pedriatic Vse

Safety and effectiveness in children have not been established.

#### **ADVERSE REACTIONS**

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

#### DOSAGE AND ADMINISTRATION

The suggested dose range for i.v. administration, after reconstitution with oxidant-free sodium pertechnetate Tc 99m Injection, to be employed in the average patient (70 kg) is:

Bone imaging: 10-20 mCi Technetium Tc 99m Medronate

Scanning post-injection is optimal at about 1-4 hours.

Slow administration of the drug over a period of 30 seconds is recommended.

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 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**

Diagnostic Isotopes' Technetium Tc 99m Medronate Kit is supplied as a sterile, pyrogen-free kit containing 10 vials.

Each 10 ml vial contains 10 mg medronic acid, 0.17 mg (minimum) stannous chloride (maximum stannous stannic chloride 0.29 mg), and 2 mg ascorbic acid. The pH has been adjusted to 4-8 with either HCl or NaOH prior to lyophilization. Following lyophilization, the vials are sealed under a nitrogen atmosphere.

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\*G. Subramanian, et al: Technetium-99m Methylene Diphosphonate — A superior agent for skeletal imaging. Comparison with other Technetium complexes. J. Nucl Med 16:74, 1975

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#### INDICATIONS

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**CONTRAINDICATIONS** - None.

#### WARNINGS

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

Ideally, examinations using radiopharmaceuticals, especially those elective in nature, on a woman of childbearing capability should be performed during the first few (approximately 10) days following onset of 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 reactor or particle accelerator and whose experience and training bave been approved by the appropriate government 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

The test should not be started within 24 hours of a therapeutic dose (1000  $\mu$ g) of vitamin B<sub>12</sub> or within 24 hours of a loading dose of vitamin B<sub>12</sub> given for the Schilling test. If bone marrow examinations are to be done, they should precede the administration of this test, as the flushing parenteral dose of vitamin B<sub>12</sub> may alter the bone marrow picture.

ADVERSE REACTIONS - None.

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NUCLEAR MEDICINE PHYSICIAN. THE Department of Nuclear Medicine at the University of Tennessee Center for the Health Sciences has opening at Instructor or Assistant Professor level, depending upon qualifications. The department serves City of Memphis Hospital. LeBonheur Children's Hospital, and University of Tennessee Hospital. Proven ability in teaching and research and knowledge and practical experience in all major categories of Clinical Nuclear Medicine are necessary. ABNM certification or eligibility required. Send C.V. and references to Martha McDonald, MD, Acting Chairman: Department of Nuclear Medicine: University of Tennessee: 865 Jefferson, Room 150C, Chandler Building; Memphis, Tennessee 38163. The University of Tennessee is an Equal Opportunity/Affirmative Action employer.

MONTEFIORE HOSPITAL. UNIVERSIty of Pittsburgh School of Medicine is seeking a full-time faculty member to direct the Nuclear Medicine Unit of the Department of Medicine. Applicants should have experience in advanced nuclear medicine and ultrasound techniques and be prepared to develop a program involving teaching, patient care and clinical research. Replies and curriculum vitae should be sent to: Philip Troen, M.D., Physician-in-Chief, Montefiore Hospital, Professor and Vice-Chairman, Department of Medicine, 3459 Fifth Avenue, Pittsburgh, PA. 15213. University of Pittsburgh is an equal opportunity/affirmative action employer.

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and stannous chloride combine with Tc99m to form a stable soluble complex. **Clinical pharmacology:** When injected intravenously, Tc99m-labeled OSTEOSCAN has a specific affinity for areas of altered osteogenesis. Areas of bone which are undergoing neoplastic invasion often have an unusually high turnover rate which may be imaged with Tc99m-labeled OSTEOSCAN. Three hours after intravenous injection of Tc99m-labeled OSTEOSCAN, an estimated 40-50% of the injected dose has been taken up by the skeleton. At this time approximately 50% has been excreted in the urine and 6% remains in the blood. A small amount is retained by the soft tissue. The level of Tc99m-labeled OSTEOSCAN excreted in the feces is below the level detectable by routine laboratory techniques. Tc99m-labeled OSTEOSCAN is also taken up in areas of necrosis and severely injured myocardial cells. Approximately 1.5 hours following intravenous injection 0.01-0.02 percent of the administered dose per gram of tissue is taken up by an acutely infarcted myocardium. **Indications:** OSTEOSCAN 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. When used as an adjunct in the diagnosis of myocardial requirements for good myocardial imaging rates positives about 16%. False negatives has been found to be approximately 14% and false positives may be related to coronary heart disease, left ventricular aneurysms, trauma, repeated cardioversion following coronary by-pass surgery or old myocardial infarction.

infarcts. Contraindications: None known. 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. The technetium used to tag the product should be routinely tested for molybdenum and aluminum; if an unacceptable level of either is found, the technetium should not be used. Radiopharmaceuticals should be used only by physicians 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 government 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. Bone Imaging: Both prior to and following Tc99m-labeled OSTEOSCAN administration, patients should be encouraged to drink fluids. Patients should be encouraged to drink fluids. 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

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References

 Khedkar, N. et al. Presented at the 1978 Annual Meeting, SNM. Southeastern chapter.
 Arnold, J. S.: Kinetic Analysis of Bone Imaging Agents. Proceedings of First International Symposium on Radiopharmacology. Innsbruck. Austria. 1978 (to be published).

<sup>1.</sup> Fogelman, I. et al: J. Nucl. Med. 20.98, 1979



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### Xenon Xe 133 Gas<sup>+</sup>

**DESCRIPTION:** Xenon Xe 133 for diagnostic use is available as 5% gas in carbon de deluent 95%

closed outent 35%. ACTIONE: Xanon Xa 133 is a ready diffusible gas which is neither utilized nor produced by the body. It passes through cell membranes and freely exchanges between blood and tasse. It tends to concentrate more in body fat than in blood, plasma, water or protein solutions. In the concentration used for diagnostic purposes it is physiologically mactive inhald xanon Xa 133 gas will inter the alvoid rivel and enters the purimous venous orculation we the capillance. Most of the zanon Xe 133 has enters the orculation from single breath is returned to the lungs and exhaled after a single pass through the ral circulation. penç

INDICATIONS: Inhalation of zenon 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.

CONTRANSDICATIONS: To date, no known contraindications to the use of xanon Xe

Continuements represented to been reported. WARNINGS: This radiophermaceutical should not be administered to pregnant or lactat-ing women unless the benefits to be gained outweigh the potential hazards. Ideally, aurimations using radiophermaceuticals, aspecially those elective in nature, of

a woman of childbearing capability should be performed during the first few (approx-mately 10) days following the onset of the menses.

mately (10) days following the creat of the menses. Radiopharm.court.cals should be used only by physicians who are qualified by specific training in the table use and hending of radionucides produced by nuclear reactor or periodic accelerator, and whose superince and training have been approved by the appropriate governmental agency authorized to license the use of radionucides. **PEECAUTURE:** 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 man-sense. agement, and to insure minimum radiation exposure to occupational workers. Expired senon Xe 133 gas should be controlled in a manner that is in compliance with the

amon Ac 133 gas mouto de controlectin a manner marte sin companece with the appropriate governmental agency regulations. Xanon Xa 133 adheres to some plastics and rubber and should not be allowed to stand in tubing or respirator containers. Such unincogeneol loss of radioactivity from the does for administration may render the study nonlagnostic. Xenon Xa 133 ad elevery systems, e, respirators or sprometers, and associated tubing assembles must be

### **PULMOLITE**<sup>™</sup>

### Technetium Tc 99m Aggregated Albumin Kit August 1976

DIAGNOSTIC-FOR INTRAVENOUS USE

Descrimination of the second s preserving of stances chande dhydrate. PULMOLITE is propertied from abumm That was nonrescue when tested for hepatris B antigen (HByAg) by radiommunoassey. Each valid content 3.6.5.5.10° aggregated abumn particles. The patrice see distribution of the aggregated abumn as such that not less than 85% are within the range of 15-80 microns in zerons and the distribution of the aggregated abumn patrices green that the remons in zerons in

### PHYSICAL CHARACTERISTICS

Technology Technology is the set of the set

### Table 1 Brinsials Radiation Emission Rate

Redietion	Mean %/ Disintegration	Mean Energy (keV)
Gemme ?	87.9	140.5
(1) Dilman, L.T. and Van der & Parameters for Use in Radiatio	age, F.C. Radionuclide Decay Schemes in-Dose Estimation, MIRD Pamphiet No	and Nuclear . 10, p. 62.

### EXTERNAL RADIATION

The apecific germa ray constant for LS 9m s 0.8/r/mC-hr at 1cm. The first half velue thickness of lead (Pb) for Tc 99m is 0.2mm. A range of values for the inlative attenuation of the radiation emitted by the radionucled that results from interposition of uningui thicknesse of Pb is shown in Table 2. For sample, the use of 2.7mm of Pb will decrease the esternal radiation seposure by a factor of about 1,000.

Table 2. Rediction Attenuation by Lead Shelding Sheld Thickness (Pb) mm Coefficient of Attenuation			
0.2	0.6		
0.95	10-1		
1.8	10-1		
27	10-1		
3.8	10-1		
Ĩ Ś.	10-4		

To correct for physical decay of this radionuclide, the fractions that remain at selected time intervals after the time of calibration are shown in Table 3.

h	ible 3. Physical Decay Char Fraction	t: <b>To 99m</b> Half-Life	6.03 Neura Fraction
Hours	Remaining	Hours	Remaining
0'	1,000	8	399
Ň	891	ĝ	365
2	795	10	317
Ĵ.	708	11	282
Ä	631	12	262
6	583		
Ă	502		
3	447		
*Calibration T	me		

CLINICAL PHARMACOLOGY: Within 5-10 minutes of intravenous injection, over 90% Common reasonable to the initial set of the set of t

(1975)

Europe: NEN Chemicals GmbH, D-6072 Drawich, W. Germany, Postfach 401240 Tel (06103) 85034 Order Entry: (06103) 81011

lexproof to evoid 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 xanon

Xe 133 ges have been reported. DOSAGE AND ADMINISTRATION: Xenon Xe 133 ges is administered by inhelation

The suggested activity range employed for inhalation by the average adult patient

(70 kg) is Puimor Pulmonary function including imaging: 2-30 mCi in 3 liters of air. Cerebral blood flow: 10-30 mCi in 3 liters of air.

The parent does should be massured by a suitable radioactivity calibration system immediately pror to administration. **PHYBICAL CHARACTERESTICE:** Xenon Xe 133 decays by beta and gemma emissions with a physical half-life of 5.27 days (1). Photons that are useful for imaging studies are listed in Table 1.

Table 1 Radiation	. Principal Radiation Emission Data X Mean % per Disintegration	enen Xa 133 Mean Energy (keV)
Beta-2	99.30	100.6
Gemma-2	34.99	81.0
K int. con. electrons,-2	47.24	45.0
L int. con. dectrons,-2	7.87	75.7
M int. con. electrons,-2	9.84	80.0
K x-rays	34.70	30.8
K x-ravs	7.67	35.2

(1) Deman, L.1., Radionuclide Decay Schemes and Nuclear Parameters for Use in Radiabon-Dosa Estimation, Part 2, Supplement No. 4, MIRD pamphlet No. 6, J. Nucl. Med., p. 28, 1970. The specific gamma ray constant for senon Xe 133 is 0.44 R/mCi-hr. at 1 cm. The hair value layer is 1 mm of Pb. In promet the physical distribution.

orrect for physical decay of this radionucide, the fractions that remain at selected ervals before and after the date of calibration are shown in Table 2. To come

Lung to liver ratios of about 19:1 are obtained within the first few minutes. Emmasion of the TC 99m aggregated albumin from the lungs occurs with a hell-the of about 5.6 hours. Cumulative unnery escription studies show an everage of 20% elimina-tion of the rejected TC 99m dose 24 hours post administration.

Ten of the injected is takin does on ours post commisterion. MeDiCATIONS AND USASE: Unchratum, Te Sydm aggregated abumm is indicated as a lung imaging agent to be used as an adjunct in the evaluation of pulmonary partition. CONTRANDICATIONS: Technotum, Te Stim aggregated abumm should not be adminis-teed to patients with severe pulmonary hyperimension. The use of Ic SSm aggregated abumm is contrandicated in persons with a history of

mections to products containing human serum a NES: The possibility of allergic reactions should be considered in petients who

where we making is deas. Theoretically, the nitravenous administration of particulate material such as aggregated albums imposes a temporary small mechanical impedment to blood flow. While the effect is probably physiologically insignificant in most patents the administration of aggregated albums in possibly heardows in actus cor pulmonale and other states of severally impared pulmonary blood flow.

severaly impaired pulmonary blood flow. The redispharmaceutical preparation should not be administered to children or to pregnent or lactating women unless the expected banefits to be gained outweigh the

iential risks. Ideally, exem

program in the sensity evolver benear the spectral sensities to be game obviewing the lideally, examinations using radiophermicculticals, expectally those elective in neture, of a woman of childberring capability should be performed during the first few (approx-mately 10) days following the onset of menass. **PRECAUTRONS:** In cases of night-to-left cardac shunt, additional nak may east due to the rapid mitry of aggregated abumin into the systemic circulation. The contents of the first are not radioactive. However, after the sodium perfectine real cardioactive the systemic cardioactive interview of the systemic cardioactive. The contents of the first are not radioactive. However, after the sodium perfectine test and the systemic cardioactive interview of the systemic cardioactive. The labeling reactions evolved in propering the agent depend on mantening tim in the reduced state. Any couldn't properies days: Hence, sodium perfectinets to BBm containing balants, or other additives, should not be employed without this domonistra-tion other additives, should not be explored without this domonistra-tion of the radioactive. It is essential that the user fellow the directions carefully and adhere to since aspect procedures during grants.

Notice the radiodences. Technetium is descently and extent to state segments and as such the paracles well settle with time. Fature to mix the val contents adequasely before use may result in non-uniform distribution of indicactions. It is also recommended that, because of the increasing probability of agglomeration with aging, a betch of fechnetium Tc 98m aggregated albumm one be used after eight hours from the time of increastitution. Refingerate at 2° to 8°C after reconstitution. If blood a wethdrawn into the symage, unnecessary datey prior to injection may result in ob-formation in adu. formation in situ

formation in seu. The contents of the wal are under a netrogen atmosphere and should be protected from an Do not use if clumping or loarning of the contents is observed. Adequate reproduction studies have not been performed in animals to determine whether this drug affects firstly in mails or themals. Nas teargoine potential, or has other adverse effects on the fistur. Technetum Tc 99m aggregated albumm should be used in pregnant women only when clearly needed. It is not hown whether this drug is succreated in humen milt. As a general rule, nursing should not be undertaken while a patient is on a drug since many drugs are excited in human milt.

It is not known writtere this brug is increase in numer mar. As genetic hus, nursing should not be undertaken while a patient is on a drug since many drugs are excreted in human mak. Selety and effectiveness in children have not been established. As in the use of any radioactive material, care should be taken to minimize radiation appointe to the patient, consistent with proper management, and to insure minimum ratification patients in should be taken to minimize radiation appointe to the occupitorial works. Radiopharmacuticals should be used only by physicians who are guarted by training and segmence and segmence in the safe use and handling of radionuclides and whose expenses to the occupitorial works. Radiopharmacuticals should be used only by physicians who are guarted by training and segmence in the safe use and handling of radionuclides and whose expenses the use of radionuclides. The iterature contains reports of deaths occuring after the edministration of appressible whoming to radionuclides in the appropriate governmental severe pubmonary hypertension. Instances of hemodynamic or disovinciant resolution to proparations of Tc Bilm-labele aggregated shorms to patients with protein-containing materials used as the safe to be applied by training to use. Boyotabel adgregated shorms to use montain the patient may the termination of appressions of Tc Bilm-labele aggregated shorms to patient protein-containing materials used as the safe aggregated shorms to the termination of appressions of Tc Bilm-labele aggregated shorms to the termination of appressions of the safe aggregated shorms to the solution of the deserver patient (TCB) is the termination of the appressions of the safe aggregated aggreg

DOSAGE AND ADMINISTRATION: The recommended intravenous dose range for the average patient (70kg) is 1 to 4 milliounes. The volume of the dose may vary from 0.2 to 1.3ml

### Table 2. Xanan Xa 133 Physical Bocay Chart (Ital-Ille 5.27 days) Fraction

Day	Remaining	Day	Remaining
.5	1.930	8	.349
4	1.693	9	.302
-3	1.483	10	.288
-2	1.300	11	.235
-1	1.140	12	.206
0.	1.000	13	.181
1	.877	14	.159
2	769	15	139
3	.674	16	122
4	.591	17	107
5	518	18	.094
6	.454	19	.082
7	.398	20	.072
*Calibration	Dav		

rtion

Calification Day RADATION DESIMETRY: The estimated absorbed radiation doses (2) to an average patient (70 kg) for pulmonary perfusion and carebral blood flow studies from a maxim dose of 30 milliouries of zenon Xe 133 in 3 liters of ar are shown in Table 3.

	Table 3. Red	lation Deco	1	
	Effective Half-time	Lungs*	Brain	Whole Body
		rads/	30mCı	
Pulmonary Perfusion Cerebral Blood Flow	2 mm. 5 min.	0.25 0.63	0.0014 0.0035	0.0027 0.0068
*99% of activity is in lungs				

(2) Method of Calculation: A Schema for Absorbed-Dose Calculation for Biologically Distributed Redionuclides, Supplement No. 1, MIRD pemphiet No. 1, J. Nucl. Med., p. 7. 1968

7, 1950. MOW SUPPLIED: The zenon Xe 133 gas is supplied as part of the Calidose® system, consisting of 2 ml unit does wats and the Calidose disponser\* for shalded dispensing. Normally visis containing either 10 or 20 mCi/visi, packed up to 5 viels per shald tube, are supplied. Visi sets containing up to 100 mCi/visi are evaluate.

\*Patent Panding \_ \*JO 127 July 1975, Rev 1

The recommended number of eggregated albumsn particles to be administered per dose is 200,000-700,000 with the suggested number being approximately 350,000. For easie and accutecy in disponent (the properied agent, it is recommended that to to reconstruction, concentrated addum percenterate to Pathone be further disponent to volume of 8ml with fresh, preservative-fine sodium chiende impection (U.S.P.). nd that price

Table 4.	Partialas/Base	x 10** (T =	5 x 10 <sup>+</sup> norticies/visit

econstitution	Dase			
ctivity (mCi)	1 mCi	2 mCi	3mCi	4mCi
20	0.25	0.50	0.76	1.0
30	0.17	Ŏ.33	0.60	0.67
40	0.13	0.25	0.38	0.50
60	0.10	0.20	0.30	0.40

### RADIATION DOSIMETRY

The estimated absorbed radiation doses (1) to an everage patient (70kg) from an intravenous injection of 4 milliounes of Tc 99m appregated albumin are shown in Table 5

Table 5. Rediction	loos	
	<b>Rediction Absorbed</b>	Does (reds/4mCi)

	Kediation Absorbed Does (Face/		
Lungs	1.04		
Whole Body	0.06		
Lwar	0.12		
Spieen	0.11		
Bladder Well 2 hour void	0.08		
4.8 hour yold	0.11		
Ovanes	0.08		
Testes	ň ň7		

(1) Method of Calculation: A Scheme for Absorbed-Dose Calculations for Biologically Destructed Redonuctides, Supplement No. 1, MRD Pemphiel No. 1, p. 7, (1956), MOW SUPPLIEB: PULMOLITE<sup>®</sup> Technetium Tc 99m Appropried Abumin Kit is suppli-in Just of Juy (5) or Intry (30) web, sterile and non-progenic, soch will centianing in Just of Juy (5) or Intry (30) web, sterile and non-progenic, soch will centianing in a last of Juy (5) or Intry (30) web, sterile and non-progenic, soch will centianing in a last of Juy (5) or Intry (30) web, sterile and non-progenic, soch will centianing in a last of Juy (5) or Intry (30) web, sterile and non-progenic, soch will centianing in a last of Juy (5) or Intry (30) web, sterile and non-progenic and the soch will centianing in a last of Juy (5) or Intry (30) web, sterile and non-progenic and the soch will centianing in a last of Juy (5) or Intry (30) web, sterile and non-progenic and the soch will centianing in a last of Juy (5) or Intry (30) web, sterile and non-progenic and the soch will centianing in a last of Juy (5) or Intry (30) web, sterile and non-progenic and the soch will centianing in a last of Juy (5) or Intry (30) web, sterile and non-progenic and the soch will centianing in a last of Juy (5) or Intry (30) web, sterile and non-progenic and the soch will be a last of Juy (5) or Intry (30) web (30 ed form: **bed** 

Aggregated abumin (human)-1.0mg Normal human sarum albumin-10mg Sodum - khonds-10mg Stannous chlonds dehydrats, maxmum-0.07mg Each val contains 3.8-8.5 to 10° aggregated albumin particles . PULMOUTE contains on preservative, after reconstruction the shelded wal should be stored at 2 \* to 8 \* C. Included in each from (50) wal bit is one (1) package insert and six (8) radiation labels

stored at 2 to a 6. Included in each five (5) well bt is one (1) package insert and au (6) radiation labels. Included in each thirty (30) well bt is one (1) package insert and thirty-su (36) radiation

DIRECTIONS Asophically inject approximately Brid of sodium partechnetate Tc 99m, containing about 20 to 50 milliounis (pre-divide with starile, preservative-free salive as necessary) into a shadded val of PLLADUITE.

anisotion will of PULNIUTE. NOTE: Entrie the well septum with the needle at an oblique angle and add the pertechna-tiss solution in such a way that it first strikes the well wall. Shake vegorquary for at least 30 seconds before use. Complete the Redealant Label provided and apply to shadd. Prov to withdrawing an alquot, re-suspend the particles by repearedly investing the shadded well or 15 seconds. After reconstitution, store at 2\* to 8\*C and use the properties

within a ghit hours. This reagant kit is approved for use by parsons beamad by the U.S. Nuclear Regula-tory Commission pursuant to Section 35-14 and 35-100 Group III of 10CFR 35 or under learnes of Agreement States.

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