If you are administering Metastron® to relieve metastatic bone pain, accurate measurement of Sr-89 before patient administration is essential. Capintec's BETA-C meets FDA and new NRC Part 10, Section 35.52 regulations.

As the leading manufacturer of dose calibrators, we recognize that to be consistently accurate in counting betas requires something different than the deep well ion chamber of a conventional dose calibrator. It also needs more than the touch of a button to accurately measure beta activity in a syringe and a vial. The BETA-C counts betas such as Sr-89 and P-32 with the speed and accuracy you expect from Capintec.

- Designed for fast, accurate dose determination in both syringes and vials.
- NaI crystal detector eliminates geometry and gamma contamination problems.
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The BETA-C meets FDA Requirements for 510K Equivalency. With the BETA-C Dose Calibrator you are assured of meeting existing and future regulatory requirements.

Join more than 8000 of your colleagues in celebrating the 42nd Annual Meeting of the Society of Nuclear Medicine in Minneapolis, Minnesota, June 11-15, 1995. Participate in the intensive educational program, review posters, discuss the most recent developments with colleagues, and join any of a host of much talked about extracurricular activities. Don't miss this opportunity to learn, mingle with your colleagues, and visit with exhibitors.

Refresher and state-of-the-art continuing education courses in chemistry, physics, quality assurance, cardiovascular nuclear medicine, PET, SPECT and NMR will supply up-to-the-minute approaches and procedures for all clinical settings.

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The years presentation of over 1000 scientific papers and posters includes a distillation of the latest advancements and finest work achieved by outstanding scientists and physicians in the field of nuclear medicine. These papers, presented by the original authors, with over 30 subjects to choose from, will provide a unique opportunity for enhancing your knowledge or exploring new avenues in correlative areas of nuclear medicine. Ample time is allotted at these presentations for questions and discussions. An extensive display of scientific posters and exhibits will augment the presentation. The ever-increasing importance of the role of the nuclear medicine technologist will be explored in our Technologist Program. Over 70 hours of clinical updates will provide chief and staff technologists with the latest in basic, intermediate, and advanced studies. This program will broaden expertise and enhance the technologist's contribution to nuclear medicine.

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The Society of Nuclear Medicine is continuously adding to its library of audiovisuals, books, and other publications. A stop at the publications booth is well worth the time. Here you will find on display what the Society has to offer for year-round educational advancement. Networking opportunities and job referral boards are available at special locations throughout the meeting as well as membership information at our membership booth.

**EXHIBIT**

All the major manufacturers of nuclear medicine products and services—more than 100 in all—will be on hand to explain and demonstrate the most technologically-advanced equipment. Several companies will present User Meetings to give an in-depth understanding of their products.

<table>
<thead>
<tr>
<th></th>
<th>Before May 5</th>
<th>After May 5</th>
</tr>
</thead>
<tbody>
<tr>
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<tr>
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</tr>
</tbody>
</table>

If you need further information, please contact:

**Society of Nuclear Medicine**

Department of Meeting Services
1850 Samuel Morse Drive, Reston, Virginia 22090-5316
(703) 708-9000 Fax: (703) 708-9015
STEP" A thousand clinical cases later.

"We do perform 360-degree rotation with STEP and we feel that the additional data acquired is very helpful."
Stuart Gottlieb, M.D., Mercy Outpatient Center, Nuclear Cardiology Laboratory, Miami, FL.

"The STEP technique has had a significant effect on the accuracy of our diagnosis in our laboratory..."
Fred Datz, M.D., Professor of Radiology, Director of Nuclear Medicine, University of Utah School of Medicine, Salt Lake City, UT.

"Our preliminary comparison of STEP with standard imaging and cardiac catheterization in over 300 patients suggests that STEP appropriately eliminates attenuation artifacts."
Timothy Blackburn, M.D., Research Medical Center, Kansas City, MO.

Blue area in 3-D rendered conventional thallium image represents decreased activity in the inferior wall due to diaphragmatic attenuation. (Also seen in short axis slice.)

STEP eliminates artifact, clearly showing normal perfusion in the inferior wall area of 3-D rendered STEP image. (Also seen in short axis slice.)

*Conventional SPECT.*

Over a thousand plus clinical cases later, STEP is clearly superior to conventional nuclear imaging. Within the past year, we took a giant STEP forward to develop a proven track record for non-uniform attenuation correction in myocardial perfusion imaging. And we have hundreds of cases to prove it. How about the competition?

Simultaneous transmission Emission Protocol (STEP) was also the first commercially available non-uniform attenuation correction device for 360-degree cardiac SPECT. This leading-edge technology is just another one of those industry firsts you've come to expect from us. For clinical proof, call Picker today at 1-800-323-0550.

Picker International, 595 Miner Road, Cleveland, Ohio 44143.

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Picker is certified ISO 9001 for meeting internationally recognized quality standards.

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It's not over until you get past the artifacts

When female and large-chested or obese male patients undergo myocardial perfusion imaging, there is the potential for images to be peppered with artifacts—possibly resulting in inconclusive studies.

Cardiolite® comes through, especially in these patients. The higher photon energy (140 keV) provides greater anatomical detail to enhance interpretive confidence—which may reduce false-positives and equivocal cases.

Cardiolite also offers the unique advantage of direct measurement of both myocardial perfusion and ventricular function from one study.

So rather than settle for potentially inconclusive images, use Cardiolite and reduce soft-tissue attenuation.

Please see us at the SNM Annual Meeting. Island #909

Cardiolite®
Kit for the preparation of Technetium Tc99m Sestamibi

To reduce soft-tissue attenuation
Cardiolite comes through

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Stress testing should be performed only under the supervision of a qualified physician in a laboratory equipped with appropriate resuscitation and support apparatus. There have been infrequent reports of signs and symptoms consistent with seizure and severe hypersensitivity after administration of Tc99m Sestamibi.

Please see brief summary of prescribing information on adjacent page.
Cardiolite®
Kit for the preparation of Technetium Tc99m Sestamibi

F O R  D I A G N O S T I C  U S E

DESCRIPTION: Each 5mCi vial contains a sterile, non-pyrogenic, lyophilized mixture of: Tetrakis (D-ethoxyisobutyl) stannous (9) Tetrakis (D-lyophylized) Copper (I) tetrufuroacetate - 0.1mg Sodium Citrate Dihydrate - 2.6mg L-Cysteine hydrochloride Monohydrate - 1.0mg Mannitol - 20mg Stannous Chloride, Dihydrate, minimum (SnCl2 • 2H2O) - 0.052mg Stannous Chloride, Dihydrate, maximum (SnCl2 • 2H2O) - 0.086mg Tin Chloride (Stannous and Stannic) Dihydrate, maximum (SnCl2 • 2H2O) - 0.0086mg

Prior to lyophilization the pH is 5.3-5.9. The contents of the vial are lyophilized and stored under nitrogen.

This drug is administered by intravenous injection for diagnostic use after reconstitution with sterile, non-pyrogenic, oxoid-free Sodium Perchlorate Tc99m Injection. The pH of the reconstituted product is 5.5 (0.5-0.1). No bacteriostatic preservative is present.

The precise structure of the technetium complex is Tc99m(MIBI)₂; where MIBI is 2-ethoxyisobutyl stannous.

INDICATIONS AND USAGE: CARDIOLITE®, Kit for the Preparation of Technetium Tc99m Sestamibi is a myocardial perfusion agent that is used in the evaluation of ischemic heart disease. CARDIOLITE®, Kit for the Preparation of Technetium Tc99m Sestamibi is useful in distinguishing normal from abnormal myocardium and in the localization of the abnormality, in patients with suspected myocardial infarction, ischemic heart disease or coronary artery disease. Evaluation of ischemic heart disease or coronary artery disease is accomplished using rest and stress techniques.

CARDIOLITE®, Kit for the Preparation of Technetium Tc99m Sestamibi is also useful in the evaluation of myocardial perfusion using the first pass technique.

Rest-exercise imaging with Tc99m Sestamibi in conjunction with other diagnostic information may be used to evaluate ischemic heart disease and its localization.

In clinical trials, using a template consisting of the anterior wall, inferior-posterior wall and isolated apex, localization in the anterior or inferior-posterior wall in patients with suspected angina pectoris or coronary artery disease was shown. Disease localization isolated to the apex has not been established.

Tc99m Sestamibi has not been studied or evaluated in other cardiac diseases.

It is usually not possible to differentiate recent from old myocardial infarction or to differentiate recent myocardial infarction from ischemia.

CONTRAINDICATIONS: None known.

WARNINGS: In studying patients in whom cardiac disease is known or suspected, care should be taken to assure continuous monitoring and treatment in accordance with safe, accepted clinical procedure. Infrequently, death has occurred 4 to 24 hours after Tc99m Sestamibi use and is usually associated with exercise stress testing (See Precautions). PRECAUTIONS:

GENERAL

The contents of the vial are intended only for use in the preparation of Technetium Tc99m Sestamibi and is not to be administered directly to the patient without first undergoing the preparative procedure.

Radioactive drugs must be handled with care and appropriate safety measures should be used to minimize exposure to care personnel. Also, care should be taken to minimize radiation exposure to the patients consistent with proper patient management.

Contents of the kit before preparation are not radioactive. However, after the Technetium Tc99m Sestamibi Injection is added, adequate shielding of the final solution must be provided.

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

Technetium Tc99m labeling reactions involved in maintaining the stannous ion in the reduced state. Hence, solution containing Technetium Tc99m Sestamibi should not be used.

Technetium Tc99m Sestamibi should not be used more than six hours after preparation.

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 and maintained. Use of radiouclides.

Stress testing should be performed only under the supervision of a qualified physician and in a laboratory equipped with appropriate resuscitation and support apparatus.

The most frequent exercise stress test endpoints, which resulted in termination of the test during controlled Tc99m Sestamibi studies (two-thirds were cardiac patients) were:

- Fatigue 35%
- Dyspnea 17%
- Chest Pain 16%
- ST-depression 7%
- Arrhythmia 1%

Cardiogenic M writigation, Immunosuppression of Fertility

In comparison with non-technetium labeled radiopharmaceuticals, the radiation dose to the ovaries (1.5-rad/mCi) at rest, 1.2 rad/mCi (at exercise) is high. Minimal exposure (ALARA) is necessary in women of childbearing capability. (See Dosimetry subsections in DOSAGE AND ADMINISTRATION section.)

The active intermediate, [CuMBI]₂BF₄, was evaluated for genotoxic potential in a battery of five tests. No genotoxic activity was observed in the Ames, CHO/HGPRT and bacterial microassay test systems at extratre.

At cytotoxic concentrations (2 μg/ml), an increase in cells with chromosome abnormalities was observed in the in vitro human lymphocyte assay. [CuMBI]₂BF₄ did not show genotoxic effects in the in vivo mouse micronucleus test at a dose which caused systemic and bone marrow toxicity (100mg/kg, > 600 × maximal human dose).

Pregnancy Category C

Animal reproduction and teratogenicity studies have not been conducted with Technetium Tc99m Sestamibi. It is not known whether Technetium Tc99m Sestamibi can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. There have been no studies in pregnant women. Technetium Tc99m Sestamibi should be given to a pregnant woman only if clearly needed.

Nursing Mothers

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

Pediatric Use

Safety and effectiveness in children below the age of 18 have not been established.

ADVERSE REACTIONS: During clinical trials, approximately 8% of patients experienced a transient paresthesia and/or taste perversion (metallic or bitter taste) immediately after the injection of Technetium Tc99m Sestamibi. A few cases of transient nausea, flushing, edema, injection site inflammation, dyspnea, nausea, vomiting, pruritus, rash, urticaria, dry mouth, fever, dizziness, fatigue, dyspnea, and hypotension, have been attributed to administration of the agent. Cases of angina, chest pain, and death have occurred (see Warnings and Precautions). The following adverse reactions have been rarely reported: signs and symptoms consistent with seizure occurring shortly after administration of the agent, transient arthritis in a wrist joint; and severe hyper-sensitivity, which was characterized by dyspnea, hypotension, bradycardia, asthma and vomiting within two hours after a second injection of Technetium Tc99m Sestamibi.

DOSAGE AND ADMINISTRATION: The suggested dose range for I.V. administration in a single dose to be employed in the average patient (70kg) is:

- 370-1110mBq (10-30mCi)

The dose administered should be the lowest required to produce a definite study consistent with ALARA principles (see also PRECAUTIONS).

When used in the diagnosis of myocardial infarction, imaging should be completed within four hours after administration.

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

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and vial permit.

Store at 25-35°C before and after reconstitution.

RADIATION DOSIMETRY: The radiation doses to organs and tissues of an average patient (70kg) per 1110mBq (30mCi) of Technetium Tc99m Sestamibi injected intravenously are shown in Table 4.

Table 4. Radiation Absorbed Doses from Tc99m Sestamibi

<table>
<thead>
<tr>
<th>Organ</th>
<th>2.0 hour void</th>
<th>4.8 hour void</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rad/s</td>
<td>mGy/30mCi</td>
<td>mGy/30mCi</td>
</tr>
<tr>
<td>Breasts</td>
<td>0.2</td>
<td>0.2</td>
</tr>
<tr>
<td>Gallbladder Wall</td>
<td>4.6</td>
<td>4.6</td>
</tr>
<tr>
<td>Small Intestine</td>
<td>0.6</td>
<td>0.6</td>
</tr>
<tr>
<td>Upper Large Intestine Wall</td>
<td>2.2</td>
<td>2.2</td>
</tr>
<tr>
<td>Lower Large Intestine Wall</td>
<td>0.7</td>
<td>0.7</td>
</tr>
<tr>
<td>Stomach Wall</td>
<td>0.2</td>
<td>0.2</td>
</tr>
<tr>
<td>Large Intestine Wall</td>
<td>0.7</td>
<td>0.7</td>
</tr>
<tr>
<td>Ovary</td>
<td>0.2</td>
<td>0.2</td>
</tr>
<tr>
<td>Testes</td>
<td>0.2</td>
<td>0.2</td>
</tr>
<tr>
<td>Red Marrow</td>
<td>0.2</td>
<td>0.2</td>
</tr>
<tr>
<td>Urinary Bladder Wall</td>
<td>0.2</td>
<td>0.2</td>
</tr>
<tr>
<td>Total Body</td>
<td>0.2</td>
<td>0.2</td>
</tr>
</tbody>
</table>

Radiopharmaceutical Internal Dose Information Center, July, 1990, Oak Ridge Associated Universities, P.O. Box 117, Oak Ridge, TN 37831, (615) 576-3400

HOW SUPPLIED: Du Pont Radiopharmaceuticals’ CARDIOLITE®, Kit for the Preparation of Technetium Tc99m Sestamibi is supplied as a 5ml vial in kits of two (2), five (5) and thirty (30) vials. sterile and non-pyrogenic.

Prior to lyophilization the pH is between 5.3-5.9. The contents of the vials are lyophilized and stored under nitrogen. Store at 15-25°C before and after reconstitution. Technetium Tc99m Sestamibi contains no additives. Included in the vial and the kit are one (1) package insert, six (6) vial shield labels and six (6) radiation warning labels. Included in each five (5) vial kit are one (1) package insert, six (6) vial shield labels and six (6) radiation warning labels. Included in each thirty (30) vial kit are one (1) package insert, thirty (30) vial shield labels and thirty (30) radiation warning labels.

The U.S. National Regulatory Commission has approved this reagent kit for distribution to persons licensed to use byproduct material pursuant to section 35.11 and section 35.200 of Title 10 CFR Part 35, to persons who hold an equivalent license issued by an Agreement State, and, outside the United States, to persons authorized by the appropriate authority.

Marketed by
Du Pont Radiopharmaceutical Division
The Du Pont Merck Pharmaceutical Co.
Billerica, Massachusetts, USA 01822

3/4 Printed in U.S.A.

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Kai Lee, PhD

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- How nuclear cardiology and SPECT highlight the interaction of hardware and software in nuclear medicine.

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Katherine Rowell, MS, CNMT, Editor

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Order now. Call toll-free, 1-800-633-2665
A 51 year old female with unstable angina, hypertension and chronic obstruction pulmonary disease. Stress-rest Thallium scintigraphy revealed defects in the anterior wall and fixed defect in the inferolateral wall. PET imaging suggested hibernating myocardium in the inferior and inferolateral wall. Clinical image courtesy of Vanderbilt University Medical Center, Nashville, TN.

Helix high-versatility digital camera design provides optimal imaging performance for every isotope and energy level, up to 511 keV. Simultaneous dual-isotope SPECT acquisition of $^{18}$F-FDG and $^{99m}$Tc MIBI potentially enhances the assessment of myocardial viability - at half the conventional scanning time.
Now, when you order unit-dose radiopharmaceuticals from your Syncor pharmacy, you have the advantages of the new SECURE™ Safety Insert System. This innovative system allows for the safe and convenient disposal of your waste.

The system has a plastic insert nested inside the unit-dose shield (lead pig) to provide a protective container for pickup and disposal of your unit-dose radiopharmaceutical waste. It is designed in accordance with OSHA regulations, provides sharps containment at the patient injection site, and frees up hot-lab space.

Another example of The Service Difference™ from Syncor. For more information and questions about availability, contact your Syncor pharmacy.
Simultaneously targets all sites of metastatic bone pain.

LONG-TERM PALLIATION IN ONE CONVENIENT DOSE.

- Palliation of pain demonstrated in the majority of patients.¹ ²
- One dose of Metastron provides pain relief for an average of up to 6 months.³
- As an adjunct to radiotherapy, 63.6% of patients receiving Metastron (10.8 mCi) had reduced pain at 6 months as compared to 35.0% of patients receiving placebo (n=42).³
- Preferentially incorporates into multiple sites of metastatic bone — the dose absorbed in metastatic deposits is approximately ten times that absorbed in normal bone marrow.⁴ ⁵
ADJUNCTIVELY DELAYS THE MEDIAN TIME TO PROGRESSION OF PAIN BY 28.1 WEEKS OVER RADIOTHERAPY ALONE.

Median time to requirement for additional radiotherapy at new pain site.3

HIGHER EFFECTIVE NON-NARCOTIC THERAPY.

□ Metastron may reduce or eliminate the need for dose escalation of narcotic analgesics.13

□ Onset of pain relief is generally within 7 to 20 days — Metastron is therefore not recommended in patients with very short life expectancy.

GENERAL WELL TOLERATED.

□ A depression of white blood cell (20%) and platelet (30%) levels may occur in patients treated with Metastron — clinically significant toxicity is rare.

□ Metastron should be used with caution in patients with significantly compromised bone marrow from previous treatment. Caution should also be used in patients with platelet counts below 60,000 or white blood cell counts below 2,400.

□ Some patients have reported a transient increase in bone pain lasting 36 to 72 hours following an injection — this can usually be controlled with analgesics.

AN IMPROVED QUALITY OF LIFE FOR PATIENTS.

□ Metastron may improve patient quality of life, as measured by assessments of mood, mobility, appetite, sleep pattern, and analgesic consumption.14

From a multicenter, double-blind study of 126 patients who received a single injection of either Metastron 400 MBq, 10.8 mCi or placebo with fractionated doses of local field radiotherapy (20-30 Gy).

Please see following page for full prescribing information.

Please see us at the SNM Annual Meeting. Island #1021
Metastron\textsuperscript{\textregistered} (Strontium-89 Chloride Injection) Description: Metastron is a sterile, non-pyrogenic, aqueous solution of Strontium-89 for intravenous administration. The solution contains no preservative.

Each milliliter contains: Strontium Chloride \textsuperscript{89} 10.9 - 22.5 mg Water for injection

The radioactive concentration is 33 mCi/mL, 1 mCi/mL, and the specific activity is 2.96 - 6.17 mCi/mg, 90% radiochemical purity. The pKa of the solution is 4.7.5. Physical Characteristics: Strontium-89 decays by beta emission with a physical half-life of 50.5 days. The maximum beta energy is 0.515 MeV.

The maximum range of 0.515 MeV beta particles in a typical adult is approximately 6 mm. Radioactive decay factors are to be applied to the stated value for radioactive concentration at calibration, when calculating injection volumes at the time of administration, are given in Table 1.

<table>
<thead>
<tr>
<th>Day*</th>
<th>Factor</th>
<th>Day*</th>
<th>Factor</th>
</tr>
</thead>
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<tr>
<td>24</td>
<td>1.39</td>
<td>12</td>
<td>1.18</td>
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<td>1.35</td>
<td>10</td>
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<tr>
<td>20</td>
<td>1.32</td>
<td>8</td>
<td>1.12</td>
</tr>
<tr>
<td>18</td>
<td>1.29</td>
<td>6</td>
<td>1.10</td>
</tr>
<tr>
<td>16</td>
<td>1.25</td>
<td>4</td>
<td>1.08</td>
</tr>
<tr>
<td>14</td>
<td>1.21</td>
<td>2</td>
<td>1.03</td>
</tr>
</tbody>
</table>

* Day before (or) on the day after calibration date is shown on the label.

Clinical Pharmacology: Following intravenous injection, soluble strontium compounds behave like their calcium analog, clearing rapidly from the blood and selectively localizing in bone mineral. Update of strontium by bone occurs preferentially in sites of active osteoclastosis, thus primary bone tumors and areas of metastatic involvement (tobacco smoking, chronic beryllium disease) may show significantly greater concentrations of normal bone.

Strontium-89 Chloride is retained in metastatic bone lesions much longer than in normal bone, where turnover is about 14 days. In patients with extensive skeletal metastases, over half of the injected dose is retained in the bones.

Excretion pathways are two-thirds urinary and one-third fecal in patients with bone metastases. Urinary excretion is highest in the first four to six hours following administration. Excretion is greatest in the first 2 days following injection.

Strontium-89 is a pure beta emitter and Strontium-89 Chloride selectively localizes sites of primary and metastatic bone involvement with minimal irradiation of soft tissue distant from the bone lesions. (The maximum range in tissue is 6 mm, maximum energy is 1.405 MeV). Measured radiation doses are listed under the Radiation Dose section.

Clinical trials have examined relief of pain in cancer patients who have received therapy for bone metastases (neural radiation to indicated sites but in whom persistent pain recurred). In a multi-center Canadian placebo-controlled trial of 136 patients, pain relief occurred in more patients treated with a single injection of Metastron than in patients treated with an injection of placebo. Results are given in the following table.

Table 1: Comparison of the number of patients treated with Metastron or placebo who had pain relief and no increase in radiographic or radiographic re-treatment.

<table>
<thead>
<tr>
<th>Effect of Metastron and placebo, as adjunct to radiotherapy, on treatment outcome over time</th>
<th>Months Post Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>Metastron</td>
<td>Placebo</td>
</tr>
<tr>
<td>74.1%</td>
<td>64.1%</td>
</tr>
<tr>
<td>79.9%</td>
<td>57.1%</td>
</tr>
<tr>
<td>65.8%</td>
<td>51.0%</td>
</tr>
<tr>
<td>50.3%</td>
<td>35.2%</td>
</tr>
<tr>
<td>36.4%</td>
<td>25.0%</td>
</tr>
<tr>
<td>35.3%</td>
<td>20.0%</td>
</tr>
<tr>
<td>13.2%</td>
<td>9.0%</td>
</tr>
<tr>
<td>16.2%</td>
<td>6.7%</td>
</tr>
<tr>
<td>16.2%</td>
<td>5.0%</td>
</tr>
</tbody>
</table>

At each visit, treatment success, defined as a reduction in a patient's pain score without any increase in radiographic activity and without any supplementary radiotherapy at the index site, was more frequent among patients assigned to Metastron than Placebo. The number of patients classified at each visit as treatment successes who were pain free at the index site and did not require analgesics was consistently higher in the Metastron group.

In another clinical trial, pain relief was greater in a group of patients treated with Metastron compared with a group treated with non-radioactive strontium-89.

Indications and Uses: Metastron-89 Chloride Injection is indicated for the relief of bone pain in patients with painful skeletal metastases. The presence of bone metastases should be confirmed prior to therapy.

Contraindications: None known.

Warnings: Use of Metastron in patients with evidence of extensively compromised bone marrow from previous therapy or disease induction is not recommended unless the potential benefit of the treatment outweighs its risks. Bone marrow toxicity is to be expected following the administration of Metastron, particularly white blood cells and platelets. The extent of toxicity is variable: in patients who receive the recommended therapeutic blood cell counts are maintained at or near normal every other week. Typically, patients will be depilated by about 30% compared to pre-administration levels. The nadir of platelets is commonly sustained or approached between 12 to 13 days following injection. While white blood cells are usually depressed to a varying extent compared to pre-administration levels. Thereafter, recovery occurs slowly, typically reaching pre-administration levels six months after treatment unless the patient's disease or additional therapeutic intervention.

In considering repeat administration of Metastron, the patient's hematologic response to the initial dose, current patient status, and bone marrow suppression should be carefully evaluated.

Verifications of dose and patient identification is necessary prior to administration because Metastron delivers a relatively high dose of radioactivity.

Metastron may cause test hem at administration to a pregnant woman. There are no adequate and well-controlled studies in pregnant women. If this drug is used during pregnancy it is not known whether Metastron causes fetal harm when administered to a pregnant woman.

Precautions: Metastron should not be used in patients with cancer not involving bone. Metastron should be used with caution in patients with plasma cell disorders over 8,000 white blood cells per cu mm.

Radioactive solutions should only be used 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.

An effective way to manage metastatic bone pain.

Metastron, like other radioactive drugs, must be handled with care and appropriate safety measures taken to minimize radiation to clinical personnel.

In view of the delayed onset of pain relief, typically 7 to 20 days post injection, administration of Metastron to patients with very short expectancy is not recommended.

A calcium-like flushing sensation has been observed in patients following a rapid (less than 30-second) injection administration.

Special precautions, such as urinary catheterization, should be taken following administration to patients who are at risk of complications resulting from the risk of radioactive contamination of clothing, bed linens and the patient's environment.

Dosage and Administration: The recommended dose of Metastron is 148 MBq, 4 mCi administered by slow intravenous injection (1-2 minutes). Alternatively, a dose of 1.5 - 2.2 MBq, 0.04 - 0.06 pCi/kg body weight may be used.

Repeated administrations of Metastron should be based on an individual patient's response to therapy, current symptoms, and hematologic status, and are generally not recommended at intervals, less than 90 days.

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

Dosages and Administration: The estimated radiation dose that would be delivered over time by the intravenous injection of 37.1 mCi of Metastron to a normal healthy adult as given in Table 4. Data are taken from the ICRP publication "Radiation Dose to Patients from Radiochemical Devices" ICRP 63, Vol 15, No. 1, Page 147, Persson, Erberg, 1988.

Table 2: Strontium-89 Dosimetry

<table>
<thead>
<tr>
<th>Organ</th>
<th>mCi/Mg Urine</th>
<th>rad/cm ^3</th>
<th>Organ</th>
<th>mCi/Mg Urine</th>
<th>rad/cm ^3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kidney</td>
<td>175</td>
<td>4.7</td>
<td>Jaw</td>
<td>110</td>
<td>4.7</td>
</tr>
<tr>
<td>Skin</td>
<td>28</td>
<td>1.7</td>
<td>Bone</td>
<td>360</td>
<td>10.7</td>
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</tbody>
</table>

When metallic cesium metastases are present, significant enhanced localization of the radiochemicals will occur with surprisingly higher dosages to the metastasized compared to the normal bone.

The radiation dose in handling Strontium-89 Chloride injection during dissolution and administration is negligible in comparison to that from fluorine-18. The beta emission has a range of water of about 6 mm (20%); and in glass of about 3 mm, but the bremsstrahlung radiation may augment the contact dose.

Measured values of the dose on the surface of the unlabeled vial are about 65 mCi/mg (2.2 mg/cm \^2). It is recommended that the vial be kept sealed to transit contact shield whenever possible.

Newly Supplied: Metastron is supplied in a 10 mL vial containing 148 MBq, 4 mCi. The vial is shipped in a transportation case containing a low activity 3 mm lead and two tissue equivalent absorbers. The lid and its contents should be stored inside its transportation container at room temperature (15-25°C).

This product is licensed by the British Department of Nuclear Safety for distribution to licensed purveyors to 32 Wisconsin. Code 330.290 (a) and Part 33 Subpart F.335.5010 or under equivalent licenses of the EEC or an Agreement State.

THIS PRODUCT INFORMATION UPDATED JUNE 1993.

Manufactured by: Ameron International plc.
2636 S. Clearbrook Drive
Arlington Heights, Illinois 60005

Product Code: SML2.5PA

References:

Ameron Healthcare
2636 S. Clearbrook Drive
Arlington Heights, IL 60005

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Circle Reader Service No. 128
The Next Generation
TRIAD XLT 20 Whole Body SPECT
Superior Imaging Through Clinical Validation

Best Image Resolution
- PROXIMA Real-time Auto Body-Contouring
- Center-of-Rotation and Axial Alignment accuracy guaranteed to 0.1 mm rms
- Angular accuracy guaranteed to 0.1° rms
- Patented linearity and X-Y shift correction

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- Whole Body SPECT multiple FOV SPECT
- 511 keV F-18 FDG SPECT
- Gated Cardiac SPECT/ Ejection Fraction

Imaging Complete Patient Population
- Industry-best 20 in. axial FOV
- Industry-best 30 in. patient imaging aperture
- 500 lb. patient weight capacity
- 6 ft. 4 in. patient height imaging capacity

Best Clinical Throughput
- Entire torso SPECT in one rotation
- Entire torso three planar views
- Six-view Whole Body Scan in 22 minutes
- Whole Body SPECT up to 6 ft. 4 in.
- Optimized for Oncology Applications

Patient Comfort
- 36 in. Open Access Gantry
- Elegant "Whisper-Quiet" Operation
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Efficient Clinical Operation
- QuickVIEW Swing Arm P-scope
- Automated Pre-Scan System Setup
- Simple Protocol-based Scan Setup
- State-of-the-art Sun computing speed

First Communications of Multi-Site Clinical Validation Results From TRIONIX. Spring, 1995
TRIONIX Technical Notes: Vol 2, No. 1
Worldwide Validation Track Record Communication
of TRIAD XLT Products

-Triple Crown Results-
• Excellent Image Resolution:
• High Clinical Throughput:
• Elegant Whisper-Quiet Operation:
• F-18 FDG SPECT at 10 mm FWHM Resolution:

-Benefits-
Better Diagnostic Detection
Better Clinical Revenue
Better Patient Acceptance
Metabolic Imaging Reality

TRIAD XLT 20", Whole Body SPECT

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TRIAD XLT 9", Cardiac/Brain SPECT

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<td>Dr. Gerard</td>
<td>February 1993</td>
</tr>
<tr>
<td>Duke, Durham, North Carolina (two systems)</td>
<td>Dr. Coelman, Dr. Jaszcak</td>
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<td>University of Virginia, Charlottesville, Virginia</td>
<td>Dr. Teats, Dr. Croft</td>
<td>June 1993</td>
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<td>Memorial Mission, Asheville, North Carolina</td>
<td>Dr. Peterson</td>
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<td>Dr. Van der Wai</td>
<td>November 1993</td>
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<td>Dr. DeRoo, Dr. Mortelmans</td>
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Word-of-Mouth Marketing Program
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from A Company Driven by Quality, Business Ethics, and
Long-Term Clinical Innovation & Effectiveness
The Next Generation

TRIAD XLT 20 Whole BodySPECT

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Best Image Resolution
- PROXIMA Real-time Auto Body-Contouring
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First Communications of Multi-Site Clinical Validation Results From TRIONIX. Spring, 1995
TRIONIX Technical Notes: Vol.2, No.1
Center-of-Rotation and Axial Alignment Precision

Test Results from 10 TRIAD XLT systems
In both transverse and axial directions:
- NO max deviation larger than 0.2 mm
- NO rms deviation larger than 0.1 mm
- Average rms deviation less than 0.05 mm

Trionix engineers designed and validated “The Next Generation” TRIAD XLT 20 Whole BodySPECT imaging system to provide images of unsurpassed diagnostic detail. Superior image resolution is the result of precision system integration, both structural and system design. The solid steel single ring gantry, precision gearing, and radial motion-only detector travel, in combination with alignment digital distortion corrections (ELFS) guarantees consistent “Center of Rotation” and axial detector alignment accuracy to 0.1 mm precision.

Whole BodySPECT

Whole BodySPECT multiple FOV SPECT imaging extends the effective SPECT FOV beyond the detectors’ physical dimensions. The TRIAD XLT 20 Whole BodySPECT system provides the ability to acquire and display a 6 ft. 4 in. patient as a single SPECT study.

Whole BodySPECT is achieved by integrating a stable gantry, precise detector and table mechanical motion, and control software. The Reprojection display software presents the “entire” body on screen and allows the clinician to interactively rotate and view from any angle. This ability offers Trionix users important clinical advantages that include: whole body lesion detection, relative uptake evaluation, and new radiotracers imaging that targets tumors throughout the body.

(Area in BodySPECT FOV is dependent on patient size)
1995 SNM Abstract

SPECT Imaging by 511 keV Photons  V. Rappoport, E. Q. Chen, J. Jiang, B. Kline, C. B. Lim. TRIONIX Research Laboratory, Inc., Twinsburg, OH and Cleveland Clinic, Cleveland, OH

F-18 labeled FDG is found very useful to provide information for brain, heart and whole body studies with PET systems. We have investigated SPECT system characteristics in response to 511 keV photons on TRIAD XLT detectors with specially designed high energy collimators. Intrinsic characteristics were measured: energy resolution is $\Delta E/E = 8.96\%$; spatial resolution is FWHM 1.92 mm and 1.87 mm in UFOV and CFOV respectively. To test intrinsic planar image quality the resolution bar phantom with smallest bars of 2.12 mm width was used. The system performance was measured. The following SPECT studies were performed: four hot spheres with diameters in the range of 1.27 to 2.54 cm in 20 cm diameter cylinder filled with water; cardiac phantom in water-filled cylinder with background activity of (10:1). Cold lesion defects of dimensions 15 mm x 10 mm and 20 mm x 10 mm were inserted in the phantom. After reconstruction all spheres and both defects in cardiac phantom were clearly visible.

The reconstructed spatial resolution was measured using a Na-22 line source of 1 mm diameter. The line source was placed in the center of 20 cm diameter cylinder filled with water, and a SPECT study was performed with 11 cm distance between source and collimator surface. After reconstruction the line spread function was measured. The FWHM and FWTM were 10.2 mm and 22.7 mm respectively.

Brain and cardiac studies of the same patients were performed both on SPECT and PET systems. Comparative analysis supports the possibility of performing clinical SPECT studies with 511 keV agents. In conclusion, despite the lower sensitivity and somewhat poorer resolution, FDG SPECT studies may provide diagnostic information comparable to PET at a significantly less system cost.
TRIONIX
Worldwide Validation Track Record Communication of TRIAD XLT Products

- Triple Crown Results -
  - Excellent Image Resolution:
  - High Clinical Throughput:
  - Elegant Whisper-Quiet Operation:

- Benefits -
  - Better Diagnostic Detection
  - Better Clinical Revenue
  - Better Patient Acceptance

TRIAD XLT 20", Whole BodySPECT

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A Company Driven by Quality, Business Ethics, and Long-Term Clinical Innovation & Effectiveness
New from DuPont Radiopharmaceuticals: High Quality and Extended Stability in a SPECT Brain Perfusion Agent

JUST WHAT YOU’RE LOOKING FOR...
Introducing a NEW SPECT Brain Perfusion Agent

NEUROLITE®
KIT FOR THE PREPARATION OF TECHNETIUM Tc99m BICISATE INJECTION

Technetium Tc99m Bicisate should be used with caution in patients with renal or hepatic impairment since it is eliminated primarily by renal excretion. Adverse reactions are rare (≤1%). For details, see Adverse Reactions section of the prescribing information. In clinical trials, at least one of three readers of Neurolite® images (blinded to all other clinical information) correctly diagnosed stroke for 85% of the subjects with stroke while unblinded interpretation of CT/MRI images resulted in the correct diagnosis of stroke in 88% of subjects with stroke. There were 11 false positive and 34 false negative interpretations of Neurolite images and 0 false positive and 31 false negative interpretations of CT/MRI results.

Normal images, using Neurolite, of a 36-year-old female. — Courtesy of Thomas C. Hill, MD, Deaconess Hospital, Boston, Mass
Just what you're looking for...
HIGH-QUALITY IMAGES...
EXTENDED STABILITY...

High-Definition Perfusion Images

- Well-defined lesions
- Clear definition of perfusion defects as determined by visual analysis
- High brain-to-background activity
- Clear delineation between brain and background structures early after injection

Extended In Vitro Stability

- The SPECT brain agent with 6-hour stability after preparation
- Allows for more flexible patient scheduling
- Useful in the acute setting since doses can be prepared beforehand
- Enables SPECT brain imaging to be used with agitated or uncooperative patients where study delays are often encountered
- Allows for convenience of unit dosing

Please see brief summary of prescribing information at the end of this advertisement.
Introducing Neurolite®

JUST WHAT YOU'RE LOOKING FOR...

Desirable pharmacokinetics/dosimetry

✦ Accumulates rapidly in the brain\textsuperscript{1,2}
✦ Localizes as a function of regional brain perfusion, cellular uptake, and metabolism within the cells
✦ Rapid blood clearance—(<10\% remains in the blood after 1 minute, <5\% after 60 minutes)
✦ A dosing range of 10-30 mCi of Neurolite provides the flexibility to achieve improved image quality and/or reduced imaging time\textsuperscript{1}

Simple room-temperature preparation

One-step quality control procedure

NEUROLITE®
KIT FOR THE PREPARATION OF TECHNETIUM Tc99m BICISATE INJECTION

Quality you expect. Stability you need.

Please see brief summary of prescribing information on adjacent page.

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Neurolite\textsuperscript{®} is a registered trademark of the DuPont Merck Pharmaceutical Company.
The following is a brief summary. For more information please see complete prescribing information.

**INDICATIONS**
Neurollte single photon emission computerized tomography (SPECT) is indicated as an adjunct to conventional CT or MRI imaging in the localization of stroke in patients in whom stroke has already been diagnosed.

**PRECAUTIONS**

**USE WITH CAUTION IN PATIENTS WITH RENAL OR HEPATIC IMPAIRMENT. TECHNETIUM Tc99m BISICATE IS ELIMINATED PRIMARILY BY RENAL EXCRETION. WHETHER TECHNETIUM Tc99m BISICATE IS DIALLYZABLE IS NOT KNOWN. DOSE ADJUSTMENTS IN PATIENTS WITH RENAL OR HEPATIC IMPAIRMENT HAVE NOT BEEN STUDIED.**

Patients should be encouraged to drink fluids to and void frequently during the 2-6 hours immediately after injection to minimize radiation dose to the bladder and other target organs.

The contents of the vials are intended only for use in the preparation of Technetium Tc99m Biscosate for intravenous injection. The preparation should be administered directly to the patient without first undergoing the preparation procedure.

The contents of each vial are sterile and nonpyrogenic. To maintain sterility, aseptic technique must be used during all operations in the manipulation and administration of Neurollte.

Technetium Tc99m Biscosate should be used within six hours of the time of preparation.

As with any other radioactive material, appropriate shielding should be used to avoid unnecessary radiation exposure to the patient, occupational workers, and other people.

Radiopharmaceuticals should be used only by physicians who are qualified by specific training in the safe use and handling of radionuclides.

**CONTRAINDICATIONS**

None known.

**WARNINGS**

None known.

**DOSAGE**

**AND**

**ADMINISTRATION**

Before administration, the patient should be well hydrated. After administration, the patient should be encouraged to drink fluids liberally and to void frequently.

The recommended dose range for intravenous administration for a 70 kg patient is 370 - 1110 MBq (10-30 mCi). Dose adjustments for age, weight, gender, or renal or hepatic impairment have not been studied.

The dose for the patient should be measured by a suitable radioactivity calibration system immediately before administration to the patient. Radiochemical purity should be checked before administration to the patient.

Neurollte, like other parenteral drug products, should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

Preparations containing particulate matter or discoloration should not be administered. They should be disposed of in a safe manner, in compliance with all applicable regulations.

**PREPARATION**

**AND**

**ADMINISTRATION**

Immediately after reconstitution, vial A and vial B are stored at 15°-25°C. Protect vial A from light.

Store at room temperature (15°-30°C) after preparation.

**Dosimetry**

**CALCULATIONS**

For Dose Calculations using the MIRD software program at Oak Ridge Associated Universities, P.O. Box 117, Oak Ridge, TN 293.6.1988.

**References**


Please see us at the SNM Annual Meeting. Island #909
Greatly enhance your capacity to visualize pheochromocytoma and neuroblastoma.

I-131 MIBG
Iobenguane Sulfate I-131 Injection
Diagnostic - For Intravenous Use

I-131 MIBG was the first functional imaging agent made available for localization of pheochromocytoma and neuroblastoma. I-131 MIBG can greatly enhance your capacity to detect these tumors of adrenergic tissues.

When you combine the advantages of whole body imaging with the unique functional specificity of I-131 MIBG, you can localize extra-adrenal and metastatic pheochromocytoma in the preliminary diagnostic work-up. What's more, you can use the high sensitivity and specificity of I-131 MIBG for better management of neuroblastoma patients.

I-131 MIBG gives you a degree of diagnostic confidence simply not possible with non-radiouclide imaging techniques.

See for yourself, Call your local Syncor radiopharmacy

Manufactured in the USA by: Distributed by:

CIS-US, Inc.
10 DeAngelo Drive, Bedford, MA 01730

Syncor The Service Difference

Please see brief summary of prescribing information on reverse page.
I-131 MIBG (Iobenguane Sulfate I-131 Injection)
Diagnostic - For Intraoperative Use
Greatly enhance your capacity to visualize pheochromocytoma and neuroblastoma.

Clinical trials worldwide have demonstrated I-131 MIBG safe and effective for the localization of pheochromocytoma and neuroblastoma.

In a study of 400 cases in the US, investigators found 1-131 MIBG scintigraphy to be "the study of choice to indicate the location of suspected pheochromocytoma, giving an overall sensitivity of 78% and an overall specificity of 99%.

Neuroblastoma: Tumor Biology and Therapy, CRC Press publication states that "in many instances, the I-131 MIBG scan reveals all the [neuroblastoma] tumor deposits delineated by use of the full combination of imaging procedures ordinarily used, and this technique often reveals other [neuroblastoma] lesions not demonstrated by any other modality."

For more information: 1-800-221-7534
Manufactured in the USA by:
CIS-US, Inc.
10 DeAngelo Drive, Bedford, MA 01730

BRIEF SUMMARY
Iobenguane Sulfate I-131 Injection is a sterile, pyrogen-free radiopharmaceutical for intraoperative injection. Each milliliter contains 0.65 mg of lobenguane sulfate (0.56 mg of lobenguane iodide). Iobenguane Sulfate I-131 is also known as 131-metaiodobenzylguanidine sulfate (I-131 MIBG).

DESCRIPTION
Iobenguane Sulfate I-131 Injection is a sterile, pyrogen-free radiopharmaceutical for intraoperative injection. Each milliliter contains 0.65 mg of lobenguane sulfate (0.56 mg of lobenguane iodide). Iobenguane Sulfate I-131 is also known as 131-metaiodobenzylguanidine sulfate (I-131 MIBG).

INDICATIONS AND USAGE
Iobenguane Sulfate I-131 Injection is indicated as an adjunctive diagnostic agent in the localization of primary or metastatic pheochromocytomas and neuroblastomas.

CONTRAINDICATIONS
Iobenguane Sulfate I-131 Contraindication is contraindicated in patients with known hypersensitivity to lobenguane sulfate.

WARNINGS
As with all I-131 containing agents, in order to decrease thyroid accumulation of 131, block the thyroid gland with Iodine. (See Dosage and Administration section)

Safety, effectiveness, metabolism, urinary excretion and tumor localization are unknown in neonates.

ADVERSE REACTIONS
Transient episodes of marked hyperthyroidism have been reported in patients after injection of Iobenguane Sulfate I-131. Some of these patients were on anti-hypertensives and others were not.

Nausea, vomiting and sleeplessness have been reported after injection of higher than the recommended doses of Iobenguane Sulfate I-131. The effect level for these observations has not been identified.

Blood and bone marrow findings:
- Changes in neutrophil and platelet counts
- Eosinophilia

Other: Hypersensitivity, skin eruptions.

Table 4: Estimated Absorbed Radiation Doses:

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<td>0.01</td>
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<td>18.5</td>
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<td>2.96</td>
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<td>2.8</td>
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RADIATION DOSEMETRY
The estimated absorbed radiation doses to adults and children from an intravenous dose of Iobenguane Sulfate I-131 are shown in Table 4.


The following organs each receive less than 1 rad per procedure:
- Brain

HOW SUPPLIED:
Iobenguane Sulfate I-131 Injection is supplied in a 2 ml glass vial as a sterile, nonpyrogenic solution containing, at calibration time, 65.1 MBq/mi (3.25 MBq/ml) of Iobenguane Sulfate I-131. Store the drug at freezer temperatures (-20 to -10°C).

NOTE:
Two to three hours prior to use, place the vial in the labeled container, at room temperature. Discard the unused portion of drug after 4-6 hours if kept at room temperature.

In conformance with USP recommendations, Iodine 131 preparations should not be used after the expiration date stated on the label.

NCUK 0455670100

*This methodology was approved by the US Nuclear Regulatory Commission for distribution to persons licensed to use byproduct material listed in Section 35.279 of 10 CFR Part 35, Appendix A, April 1, 1987, as a regular equivalent.

March 1984

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Clearly demonstrates the diagnostic advantages of a new and simpler scintigraphic method for noninvasive localization of hyperfunctional parathyroid tissue. Dr. Taillefer’s presentation includes topics such as the clinical presentation and etiology of hyperparathyroidism, standardized acquisition and processing protocol, interpretation of typical case findings, and more.

Volume 3: “Comprehensive Gastric Motility Studies,” Alan H. Maurer, MD, Temple University Hospital, Philadelphia, PA.

Provides a distillation of decades of development in clinical gastrointestinal scintigraphy from Temple University Hospital, a center renowned for contributions to the subject. This pocket lecture will enable you and your colleagues to better understand this area, including clinical presentation of GI motility disorders, preparation of standardized gastric emptying acquisition protocol, processing of standardized gastric emptying studies, and more.

Volume 4: “Quantitative Cholescintigraphy,” Gerbell T. Krishnamurthy, MD, FACP, VA Medical Center, Tucson, AZ.

Dr. Krishnamurthy demonstrates optimal hepatobiliary scintigraphy technique by supplementing diagnostic images with accurate quantization of liver and gall bladder function. Shows how nuclear medicine physicians can now provide referring physicians a reproducible measure of gall bladder contractile function, which can uniquely answer many clinical questions.

FORTHCOMING IN 1995

Volume 5: “Combined Functional Perfusion Myocardial Perfusion Imaging,” Mark D. Wittry, MD, St. Louis University Hospital, St. Louis, MO.

Volume 6: “Thallium and Sestamibi Breast Scintigraphy,” Alan D. Waxman, MD, Cedars Sinai Medical Center, Los Angeles, CA.

Volume 7: “Detection of Cerebrovascular Disease with Diamox/HMPAO Scintigraphy,” Jack E. Juni, MD, William Beaumont Hospital, Royal Oak, MI.

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Amersham HEALTHCARE

SNM booth #1021

Circle Reader Service No. 126
Ceretec® Kit for the Preparation of Technetium Tc 99m Exametazime Injection

Diagnostic radiopharmaceutical – For intravenous use only

DESCRIPTION
The Ceretec kit is supplied as five packs of three vials for use in the preparation of a technetium Tc99m exametazime intravenous injection as a diagnostic radiopharmaceutical for use as an adjunct in the detection of altered regional cerebral perfusion and for the radiolabeling of autologous leukocytes. Each vial of Ceretec contains a pre-dispersed sterile, non-pyrogenic leucocyte stabilizer mixture of 0.5 mg exametazime [PdCl2(6H2O)-6HCl] (brassicamycin; Technetium Tc 99m-leucocyte eluate), 0.76 mg stannous chloride dithionate (minimum stannous tin 0.6 mg; maximum total stannous and stannic tin 4.0 µg per vial) and 4.5 mg sodium chloride, sealed under nitrogen atmosphere with a rubber closure. The product contains no antimicrobial preservative.

In addition, each package contains five 1 mL vials of Methylene Blue Injection USP 1% containing 10 mg methylene blue USP in water for injection q.s., pH adjusted with sodium hydroxide and/or hydrochloric acid, as necessary. Methylene Blue Injection USP is a sterile, non-pyrogenic solution of phenothiazin-5-ium,3,7-bis(dimethylamino)-chloride, trihydrate. Each package also contains five 4.5 mL vials of 0.003 M Monobasic Sodium Phosphate USP and Dibasic Sodium Phosphate USP in 0.9% Sodium Chloride Injection USP. The solution is sterile and non-pyrogenic. Each mL contains 0.276 mg monobasic sodium phosphate monohydrate, 0.142 mg dibasic sodium phosphate anhydrous and 9 mg sodium chloride in water for injection q.s. The total calculated osmolality of the 0.003 M Monobasic Sodium Phosphate USP and Dibasic Sodium Phosphate USP in 0.9% Sodium Chloride Injection USP is 317 mOsm/L. Each mL provides 0.285 mg (3mM) of phosphate, 0.157 mg of sodium and 0.154 mg of chloride. When used according to the preparation instructions (see Dosage and Administration), Methylene Blue Sodium Phosphate/Sodium Chloride mixture acts as a stabilizer.

INDICATIONS AND USAGE
Technetium Tc99m exametazime scintigraphy (with or without methylene blue stabilization) may be useful as an adjunct in the detection of altered regional cerebral perfusion in stroke. Tc99m exametazime without methylene blue stabilization is indicated for leucocyte labeled scintigraphy as an adjunct in the localization of intra-abdominal infection and inflammatory bowel disease.

CONTRAINDICATIONS
None known.

PRECAUTIONS
As with any injected product, acute hypersensitivity or allergic reactions are possible. Limited reports have been received of hypersensitivity reactions following administration of Tc99m labeled leukocytes prepared using Tc99m exametazime. However, the materials used in leucocyte cell separation may cause hypersensitivity reactions. It is essential that cells are washed free of sedimentation agents before they are reinjected into the patient.

In case of side effects following administration of radiopharmaceuticals, users should ensure the availability of appropriate medical treatment at the time of administration of any radiopharmaceutical to the patient.

A thorough knowledge of the normal distribution of intravenously administered technetium Tc99m exametazime injection is essential in order to interpret pathologic studies accurately. Caution should be exercised in making the final diagnosis. Results can be affected by the presence of tumor, infection, peritonitis, non-gastrointestinal or bony sites of inflammatory cell collections.

The contents of the Ceretec vial are not radioactive. After the sodium pertechnetate Tc99m is added, the product is radioactive and adequate shielding of the final preparation must be maintained. The contents of the Ceretec vial are intended only for use in preparation of technetium Tc99m exametazime injection and are NOT to be administered directly to the patient.

General
The contents of the Ceretec vial are sterile and pyrogen free. The vial contains no bacteriostatic preservative. It is essential that the user follow the directions carefully and adhere to strict aseptic procedures during preparation of the radiopharmaceutical.

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

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. Adequate hydration should be encouraged to permit frequent voiding.

Carcinogenesis, Mutagenesis, Impairment of Fertility
Long term animal studies have not been performed to evaluate carcinogenic potential or whether exametazime affects fertility in males or females. When evaluated in the Ames test, exametazime increased the apparent rate of gene mutation in the TA100 strain of S. typhimurium. Exametazime did not cause chromosomal aberrations in vitro (Chinese Hamster Ovary cells) or in vivo (rat bone marrow).

Pregnancy Category C
Animal reproduction studies have not been conducted with Tc 99m exametazime. It is also not known whether Tc99m exametazime can cause fetal harm when administered to a pregnant woman or if it can affect reproductive capacity. Therefore, Tc99m exametazime should not be administered to a pregnant woman unless the potential benefit justifies the potential risk to the fetus.

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

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

ADVERSE REACTIONS
Rash with generalized erythema, facial edema and fever has been reported in less than 1% of patients. A transient increase in blood pressure was seen in 8% of patients.

Cautionary Notes
1) 0.37 GBq up to 2.00 GBq (10 mCi to 54 mCi) technetium Tc99m may be added to the vial. Before reconstitution the technetium Tc99m generator eluate may be adjusted to the correct radioactive concentration to a volume of 5 mL by dilution with preservative-free, non-bacteriostatic saline for injection.

2) Use only eluate from a technetium Tc99m generator which was previously eluted within 24 hours. For brain imaging when using stabilizing protocol, generator eluate must not be used. For the highest radiochemical purity reconstitute with freshly eluted technetium Tc99m generator eluate. For white blood cell labeling, generator eluate must not be used after 2 hours old.

3) Radiochemical purity testing must be performed prior to patient administration. A radiochemical purity greater than 85% is necessary for product acceptance.

4) Do not use the final radiopharmaceutical preparation for Ceretec with Methylene Blue stabilizer more than 4 hours after the time of reconstitution. Do not use the final radiopharmaceutical preparation for Ceretec without Methylene Blue stabilizer more than 30 minutes after the time of reconstitution. Discard any unused material.

HOW SUPPLIED
The kit comprises five individual vials of sterile, non-pyrogenic, freeze-dried mixture of exametazime, stannous chloride dihydrate and sodium chloride, ten radiation labels, six sterile alcohol swabs, five radiochemical purity worksheets, five labeling efficiency worksheets, one package insert, five individual vials of Methylene Blue Injection USP 1%, five individual vials of 0.003 M Monobasic Sodium Phosphate USP and Dibasic Sodium Phosphate USP in 0.9% Sodium Chloride Injection USP and fifteen 0.45 μM syringe filters.

Caution: Federal (U.S.A.) law prohibits dispensing without prescription.

This reagent kit is approved for use by persons licensed by the Illinois Department of Nuclear Safety pursuant to 32 Ill. Code Adm. Sect. Section 330.256(a)(13) and 330.4010 under equivalent licenses of the U.S. Nuclear Regulatory Commission, or an Agreement State.

Patent No. 4,789,736
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Please see us at the SNM Annual Meeting. Booth #130-#132
April 17, 1995

Dear Valued Customers:

During the week of April 10th, there were questions regarding the supply of molybdenum/technetium in the United States. We are very pleased to tell you that no supply problems occurred. The Council on Radionuclides and Radiopharmaceuticals (CORAR) has initiated a collaborative effort on behalf of its members—DuPont Radiopharmaceuticals, Mallinckrodt Medical, Inc., Medi-Physics Inc., Amersham Healthcare, and Nordion International—to address these questions and ensure adequate supply of this essential product.

The manufacturers’ number one priority is to provide customers with the highest level of service, ensuring quality patient care now and in the future.

Late last week, Nordion communicated that the NRU reactor in Chalk River, Canada, experienced a production problem. Nordion informed CORAR that the mechanical system at the AECL/Nordion production reactor jammed, requiring that the reactor be shut down in order to allow personnel to service the equipment safely. Fortunately, the repairs were made and operations promptly resumed.

To provide consistent service, Nordion promptly secured an alternate source of molybdenum in Europe. In addition, CORAR contacted and worked closely with the Food and Drug Administration, as well as the Nuclear Regulatory Commission. The responsiveness of these agencies assured CORAR that the alternate material would satisfy US regulatory standards. If molybdenum production at AECL/Nordion had been interrupted, this alternate source would have been available to help fill demand for molybdenum in the United States, thereby minimizing any impact on patient care.

Again, we are pleased that you did not experience any inconvenience or disruption in molybdenum/technetium shipments. Be certain CORAR is working to provide continued reliability, utilizing several reactors to help prevent any lapse in the supply of molybdenum in the United States. If you have any questions, please contact your supplier directly at the numbers listed below.

Sincerely,
Carl Seidel, Chairman
The Council on Radionuclides and Radiopharmaceuticals*

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<th>Strip Chart</th>
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SPECT BRAIN IMAGING
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Department of Radiology Section of Nuclear Medicine

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SPONSORSHIP:
This program is sponsored by the Medical College of Wisconsin.

TUITION:
The tuition fee of $650 includes the course syllabus, handouts, breaks, breakfasts, lunches, and other amenities involved in making this a pleasant learning experience. Maximum enrollments have been established. Cancellations prior to the course will be refunded, less a $30 administrative fee.

CREDIT:
The Medical College of Wisconsin is accredited by the Accreditation Council for Continuing Medical Education to sponsor continuing medical education for physicians.

Accordingly, the Medical College of Wisconsin designates this continuing medical education activity as meeting the criteria for 13.00 hours in Category I toward the Physician’s Recognition Award of the American Medical Association.

Nuclear Medicine Technologists who attend the SPECT Brain Imaging Clinical Fellowship are eligible for 1.0 VOICE credit.

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☐ September 11-12, 1995 ☐ November 13-14, 1995

A check in the amount of $650 should accompany this registration form and be made payable to the Medical College of Wisconsin. Telephone registrations must be confirmed by check within 10 days.

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Registrations and payment should be sent to:
Lisa Ann Trembath
SPECT Brain Imaging Fellowship Coordinator
Nuclear Medicine Division
Medical College of Wisconsin
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The growth and impact of nuclear oncology is the focus of this issue of the Journal. It is dedicated to clinical and basic studies involving radionuclides, radio-labeled antibodies and somostatin analogs in diagnostic and therapeutic applications.

Significant growth has occurred in this area during the last few years, further validating the clinical efficacy of diagnostic imaging procedures, a contrast to the current healthcare environment.
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THE UNIVERSITY OF CALIFORNIA, Davis School of Medicine has a full-time faculty position available in the Nuclear Medicine Division of the Department of Radiology. Appointment will be at the Assistant Professor level (Professor of Clinical Radiology Series). Candidates must be Board certified in nuclear medicine, eligible for licensure in California, and have an academic background in nuclear medicine. Since this position will be Open Until Filled please forward curriculum vitae, a letter outlining background and interests in teaching/research and the names of five references as promptly as possible. This position is Open Until Filled, but no later than June 30, 1995. Reply to: Richard W. Katzberg, MD, Professor and Chairman, Department of Radiology, 2525 Stockton Boulevard, MSF Building, Sacramento, California 95817. The University of California is an Equal Opportunity/Affirmative Action Employer and encourages applications from women and persons of color.

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To obtain application materials, contact:

Pam Stevenson, National Institutes of Health, CC/OHRM/POS, Building 10, Room 1N312 10 Center Drive MSC 1200 Bethesda, MD 20892-0010 Telephone (301) 496-6924; Fax (301) 594-2996

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