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Cardiolite®
Kit for the preparation of Technetium Tc99m Sestamibi
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Please see reverse for brief summary of prescribing information.
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Brief Summary
Cardiolite® Kit for the preparation of Technetium Tc99m Sestamibi

FOR DIAGNOSTIC USE

DESCRIPTION: Each 5 mL vial contains a sterile, non-pyrogenic, lyophilized mixture of:
- Tetrakis (2-methoxy isobutyl isonitrile) Copper (I) tetrachlorocobaltate - 1.0 mg
- Sodium Citrate Dihydrate - 5.8 mg
- L-Cysteine Hydrochloride Monohydrate - 1.0 mg
- Mannitol - 20 mg
- Stannous Chloride, Dihydrate, minimum (SnCl2•2H,O) - 0.025 mg
- Stannous Chloride, Dihydrate, (SnCl2•2H,O) - 0.015 mg
- Tin Chloride (Stannous and Stannic) Dihydrate, maximum (as SnCl2•2H,O) - 0.006 mg

Prior to hypothylation the pH is 5.3 to 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, oxidant-free Sodium Pertechnetate Tc99m Injection. The pH of the reconstituted product is 5.3 (5.0-6.0). No bacteriostatic preservative is present.

The precise structure of the technetium complex is Tc99m[MIBI]4, where MIBI is 2-methoxy isobutyl isonitrile.

INDICATIONS AND USAGE: CARDIOLITE® Kit for the preparation of Technetium Tc99m Sestamibi, is a myocardial perfusion agent that is useful in distinguishing normal from abnormal myocardium, and in the localization of the abnormality, in patients with suspected myocardial infarction. It is also useful in the evaluation of myocardial function using the first-pass technique.

CONTRAINDICATIONS: None known.

WARNINGS: In studying patients in whom cardiac disease is known or suspected, take care to assure continuous monitoring and treatment in accordance with safe, accepted clinical procedure.

PRECAUTIONS: GENERAL

The contents of the vial are intended only for use in the preparation of Technetium Tc99m Sestamibi and are not to be administered directly to the patient without first undertaking the preparative procedure (as outlined in the full prescribing information).

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.

Contents of the kit before preparation are not radioactive. However, after the Sodium Pertechnetate Tc99m Injection is added, adequate shielding of the final preparation must be maintained.

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 depend on maintaining the stannous ion in the reduced state. Hence, Sodium Pertechnetate Tc99m Injection containing oxidants 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 authorized to license the use of radionuclides.

Cardiovascular, Mutagenesis, Impairment of Fertility

In comparison with most other diagnostic technetium-label radiopharmaceuticals, the radiation dose to the ovaries (1.5 rad/30 mCi) is high. Minimal exposure (ALARA) is necessary in women of childbearing capability. (See Dosimetry subsection in DOSAGE AND ADMINISTRATION section.)

The active intermediate, Cu(MIBI)_4BF_4, was evaluated for genotoxic potential in a battery of five tests. No genotoxic activity was observed in the Ames, CHO/HGPRT and sister chromatid exchange tests (all in vivo). At cystosyn concentrations (20 mg/L), an increase in cells with chromosome aberrations was observed in the in vivo human lymphocyte assay. Cu(MIBI)_4BF_4, did not show genotoxic effects in the in vivo mouse micronucleus test at a dose which caused systemic and bone marrow toxicity (9 mg/kg, > 3X maximal human dose).

Pregnancy Category C
Animal reproduction and teratogenicity studies have not been conducted with Technetium Tc99m Sestamibi. It is also 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.

Ideal, examinations using radiopharmaceuticals, especially those elective in nature, of a woman of childbearing capability, should be performed during the first two (approximately) 10 days following the onset of menses.

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 feedings.

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 metallic or bitter taste immediately after the injection of Technetium Tc99m Sestamibi. A few cases of transient headache, flushing and non-blooding rash have also been attributed to administration of the agent. One patient demonstrated signs and symptoms consistent with anaphylaxis, 8 to 10 minutes after administration of the drug. No other adverse reactions specifically attributable to the use of Technetium Tc99m Sestamibi have been reported.

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

The dose administered should be the lowest required to provide an adequate 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 (see also CLINICAL PHARMACOLOGY section in full prescribing information).

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 container permit.

Store at room temperature (15 to 30°C) before and after reconstitution.

RADIATION DOSIMETRY: Table 4 shows the radiation doses to organs and tissues of an average patient (70 kg) per 110 MBq (30 mCi) of Technetium Tc99m Sestamibi injected intravenously.

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></td>
<td>rad/ mCi/mg</td>
<td>rad/ mCi/mg</td>
</tr>
<tr>
<td></td>
<td>30 mCi</td>
<td>110 MBq</td>
</tr>
<tr>
<td></td>
<td>30 mCi</td>
<td>110 MBq</td>
</tr>
<tr>
<td>Breasts</td>
<td>0.2</td>
<td>0.2</td>
</tr>
<tr>
<td>Gallbladder Wall</td>
<td>2.0</td>
<td>2.0</td>
</tr>
<tr>
<td>Stomach Wall</td>
<td>3.0</td>
<td>3.0</td>
</tr>
<tr>
<td>Intestine Wall</td>
<td>5.4</td>
<td>5.5</td>
</tr>
<tr>
<td>Upper Large Intestine Wall</td>
<td>3.9</td>
<td>4.0</td>
</tr>
<tr>
<td>Intestine Wall</td>
<td>0.6</td>
<td>6.1</td>
</tr>
<tr>
<td>Heart Wall</td>
<td>0.5</td>
<td>5.1</td>
</tr>
<tr>
<td>Kidneys</td>
<td>2.0</td>
<td>2.0</td>
</tr>
<tr>
<td>Lower</td>
<td>0.5</td>
<td>5.1</td>
</tr>
<tr>
<td>Lungs</td>
<td>0.3</td>
<td>0.3</td>
</tr>
<tr>
<td>Bone Surfaces</td>
<td>0.7</td>
<td>0.7</td>
</tr>
<tr>
<td>Thyroid</td>
<td>0.7</td>
<td>0.7</td>
</tr>
<tr>
<td>Ovaries</td>
<td>1.5</td>
<td>1.5</td>
</tr>
<tr>
<td>Testes</td>
<td>0.3</td>
<td>3.4</td>
</tr>
<tr>
<td>Red Marrow</td>
<td>0.5</td>
<td>5.1</td>
</tr>
<tr>
<td>Urinary Bladder - Wall</td>
<td>2.0</td>
<td>20.0</td>
</tr>
<tr>
<td>Total Body</td>
<td>0.5</td>
<td>4.8</td>
</tr>
</tbody>
</table>


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

Prior to hypothylation the pH is between 5.3 and 5.9. The contents of the vials are lyophilized and stored under nitrogen. Store at room temperature (15 to 30°C) before and after reconstitution. Technetium Tc99m Sestamibi contains no preservatives. Included in each two (2) vial kit is one (1) package insert, five (5) vial shield labels and five (5) radiation warning labels. Included in each five (5) vial kit is one (1) package insert, five (5) vial shield labels and five (5) radiation warning labels. Included in each thirty (30) vial kit is one (1) package insert, thirty (30) vial shield labels and thirty (30) radiation warning labels.

The US Nuclear Regulatory Commission has approved this reagent kit for distribution to persons licensed to use byproduct material identified in 35.100 and 35.200 of 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.

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A safety record that spans more than a decade
I.V. Persantine® (dipyridamole USP) has a safety profile established in over a decade of clinical testing. And, based on information from over 250,000 patient studies, I.V. Persantine is generally well tolerated. Such an established record in pharmacologic stress creates a standard by which to compare other agents.

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Pharmacologic stress with I.V. Persantine takes effect smoothly with a 4-minute infusion, followed within 5 minutes with the appropriate thallium dose. This allows the patient to become accustomed to the “stressing” process more gradually: there is no “sudden impact.” Additionally, the time is short enough to allow an expedient, relatively uncomplicated imaging procedure.

Convenient, easy-to-follow protocol minimizes procedural frustrations
The procedural logistics of pharmacologic stress can be another source of emotional stress to the physician or staff. With I.V. Persantine, there’s a flexible, easy-to-follow protocol. No infusion pump needed. No need for site-specific injection. And no extra I.V. line for the imaging agent.

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*Severe adverse events have occurred infrequently (<0.3%) in a study of 3,911 patients. Patients with a history of unstable angina may be at greater risk for severe myocardial ischemia. Patients with a history of asthma may be at a greater risk for bronchospasm.

In the same study, the most frequent adverse events (<2%) were chest pain/angina pectoris, electrocardiographic changes (most commonly, ST-T changes), headache, and dizziness.


Please see brief summary of prescribing information on reverse for contraindications, warnings, and adverse reactions.
I.V. PERANTINE® (dipyridamole USP) Injection 5mg/ml

**ADVERSE REACTIONS** Adverse reaction information concerning intravenous Persantine® (dipyridamole USP) is derived from a study of 3917 patients in which intravenous Persantine was used as an adjunct to thallium myocardial perfusion imaging and from spontaneous reports of adverse reactions and the published literature.

Serious adverse events (fatal and non-fatal myocardial infarction, severe ventricular arrhythmias, and serious CNS abnormalities) are described previously (see WARNINGS).

In the study of 3917 patients, the most frequent adverse reactions were: chest pain/angina pectoris (10.4%), electrocardiographic changes (most commonly ST-T changes) (15.9%), headache (12.2%), and dizziness (11.8%).

Adverse reactions occurring in greater than 1% of the patients in the study are shown in the following table:

<table>
<thead>
<tr>
<th>Incidence (%) of Drug-Related Adverse Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chest Pain/Anxiety Pectoris</td>
</tr>
<tr>
<td>Headache</td>
</tr>
<tr>
<td>Dizziness</td>
</tr>
<tr>
<td>Electrocardiographic Abnormalities/ST-T Changes</td>
</tr>
<tr>
<td>Electrocardiographic Abnormalities/Extrasystoles</td>
</tr>
<tr>
<td>Hypotension</td>
</tr>
<tr>
<td>Nausea</td>
</tr>
<tr>
<td>Flushing</td>
</tr>
<tr>
<td>Electrocardiographic Abnormalities/Tachycardia</td>
</tr>
<tr>
<td>Dypsnea</td>
</tr>
<tr>
<td>Pain Unspecified</td>
</tr>
<tr>
<td>Blood Pressure Liability</td>
</tr>
<tr>
<td>Hypersensitivity</td>
</tr>
<tr>
<td>Persantina</td>
</tr>
<tr>
<td>Fatigue</td>
</tr>
</tbody>
</table>

Less common adverse reactions occurring in 1% or less of the patients within the study included:

Cardiovascular System: Electrocardiographic abnormalities unspecified (0.8%), arrhythmia unspecified (0.5%), palpitation (0.5%), ventricular tachycardia (0.2%) (see WARNINGS), bradycardia (0.2%), myocardial infarction (0.1% see WARNINGS), AV block (0.1%), syncope (0.1%), orthostatic hypotension (0.1%), atrial fibrillation (0.1%), supraventricular tachycardia (0.1%), ventricular arrhythmia unspecified (0.03% see WARNINGS), heart block unspecified (0.03%), cardiomyopathy (0.03%), edema (0.03%).

Central and Peripheral Nervous System: Hypotension (0.5%), hypertension (0.3%), nervousness/anxiety (0.2%), tremor (0.1%), abdominal pain (0.1%), somnolence (0.03%), dysphonia (0.03%), migraine (0.03%), vertigo (0.03%).

Gastrointestinal System: Dyspepsia (1.0%), dry mouth (0.8%), abdominal pain (0.7%), flatulence (0.6%), vomiting (0.4%), eructation (0.1%), dysphagia (0.03%), tenesmus (0.03%), appetite increased (0.03%).

Respiratory System: Pharyngitis (0.3%), bronchospasm (0.2% see WARNINGS), Hyperventilation (0.1%), rhinitis (0.1%); coughing (0.03%), urticaria (0.03%).

Other: Myalgia (0.9%), back pain (0.6%), injection site reaction unspecified (0.4%), dysphoria (0.4%), asthenia (0.3%), malaise (0.3%), arthralgia (0.3%), injection site pain (0.1%), rigor (0.1%), erache (0.1%), tinnitus (0.1%), vision abnormalities unspecified (0.1%), dysguesia (0.1%), thirst (0.03%), depersonalization (0.03%), eye pain (0.03%), renal pain (0.03%), perineal pain (0.03%), breast pain (0.03%), intermittent claudication (0.03%), leg cramping (0.03%).

OVERDOSAGE No cases of overdose in humans have been reported. It is unlikely that overdose will occur because of the nature of use (i.e., single intravenous administration in controlled settings). See WARNINGS.

Cautions Federal law prohibits dispensing without prescription.

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<table>
<thead>
<tr>
<th>Fees</th>
<th>*Early</th>
<th>Late</th>
</tr>
</thead>
<tbody>
<tr>
<td>Congress</td>
<td>$250</td>
<td>$275</td>
</tr>
<tr>
<td>Accompanying Person</td>
<td>$100</td>
<td>$125</td>
</tr>
<tr>
<td>Post Congress</td>
<td>$50</td>
<td>$75</td>
</tr>
</tbody>
</table>

*Early—before April 30, 1992

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Chairman of the Organizing Committee
Department of Nuclear Medicine
School of Medicine Padjadjaran University
Dr. Hasan Sadikin Hospital
Jalan Pasirkalihi 192 Bandung 40161 Indonesia
Tel. 62-22-85066 Fax 62-22-213937 and 62-22-211282

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Radiologist
DIRECTOR, DIVISION OF NUCLEAR MEDICINE. The Department of Radiology, Medical Center Hospital of Vermont, is seeking a radiologist as Director of the Division of Nuclear Medicine. The Director will be responsible for the organization, direction, and administration of the clinical, educational, and research missions of the Division. The proposed starting date is July 1, 1992. The successful candidate should be Board certified in Diagnostic Radiology and Nuclear Medicine or have special competence in Nuclear Medicine and should qualify for an appointment to the faculty of the University of Vermont College of Medicine. Interested candidates should forward their Curriculum Vitae to John P. Tampan, MD, Chairman, Department of Radiology, Medical Center Hospital of Vermont, III Colchester Avenue, Burlington, VT 05401. Phone: (802) 656-3592.

DIAGNOSTIC RADIOLOGIST-NUCLEAR MEDICINE. 500-bed hospital midwest-based private practice Radiology group seeking applications for a BE/BC radiologist with Nuclear Medicine competency and interest. Successful applicant will devote 50% of their time to nuclear medicine and remaining involved in diagnostic radiology. Nuclear Medicine Department utilizes state-of-the-art SPECT and planar equipment to support a wide range of imaging studies including nuclear cardiology. Equipment includes a majority of Siemens cameras and computers as well as a Trioxin Triad camera. Imaging studies available include new heart agents and monoclonal antibodies. Excellent salary, benefits, retirement and vacation. Interested candidates should send CV and references to: James E. Call, MD, Radiology Nuclear Medicine, Inc., 622 Doctors Building, 4239 Farnam Street, Omaha, Nebraska 68131.

Technologist
NUCLEAR MEDICINE TECHNOLOGIST. Med-TEAMS. The Experts in Adaptable Medical Staffing, is an established medical pool. We have the positions with assignment in Milwaukee, Waukesha and surrounding counties. Schedules from occasional to full-time to fit your personal needs. Compensation is negotiable. Requirements include being a graduate of an approved program, 2 years experience and NMTCB Registered or CNMT certified. Contact Judy Haeberle, Executive Director at (414) 544-2573.

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NUCLEAR MEDICINE TECHNOLOGIST. The Mal-inkrodt Institute of Radiology at Washington University Medical Center, St. Louis, MO, has an immediate opening for a FT registered or registry eligible technologist. Progressive department with excellent benefit package. Interested applicants call Kathleen Johnson-Brundeses at (314) 362-208. Affirmative Action/Equal Opportunity Employer. M/F/H/V

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