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INDICATIONS AND USAGE: CARDIOLITE, Kit for the preparation of Technetium Tc99m Sestamibi is a myocardial perfusion agent that is useful 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 function using the first pass technique.

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

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. Technetium 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 monitoring and treatment in accordance with accepted clinical procedures. 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 are not to be administered directly to the patient without first undergoing the preparatory procedure. 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 patient 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 prepared kit is necessary to protect personnel.

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 three hours after preparation.

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

Stress testing should be performed only under the supervision of a qualified physician and in a laboratory equipped with appropriate radiation monitoring and safety 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: 30%
- Dyspnea: 17%
- Chest Pain: 16%
- Seizure: 1%
- Arthritism: 1%

Carcinogenesis, Mutagenesis, Impairment of Fertility

In comparison with most other diagnostic technetium labeled radioisotopes, the radiation dose to the ovaries (1.3 mrad/30mCi at rest, 1.2 mrad/30mCi at exercise) is high. Minimal exposure (ALARA) is necessary in women of childbearing capability. (See Dosimetry subsection in DOSAGE AND ADMINISTRATION section.)

The active intermediate, (CuMB)BF$_4$, 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 vitro). At cytotoxic concentrations (>20 μg/ml), an increase in cells with chromosome aberrations was observed in the in vitro human lymphocyte assay. (CuMB)BF$_4$, did not show genotoxic effects in the in vivo mouse micronucleus test at a dose which caused systemic and bone marrow toxicity (90mg/kg  > 60 × 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.

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 hot or cooler area immediately after the injection of Technetium Tc99m Sestamibi. A few cases of transient headache, flushing and non-itching rash have also been attributed to administration of the agent. Cases of angina, chest pain, and death have occurred (See WARNINGS and PRECAUTIONS).

The above adverse reactions have been rarely reported: agitation, fear, anxiety, seizure occurring shortly after administration of the agent; transient arthritis in the wrist joint; and severe hypersensitivity, which was characterized by dyspnea, hypotension, hypothermia, and vomiting within two hours after administration of Technetium Tc99m Sestamibi.

DOSEAGE AND ADMINISTRATION: The suggested dose rage 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 provide an adequate study consistent with ALARA principles (see also PRECAUTIONS).

When used in the diagnostic 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 container permit.

Store at 15-25°C before and after reconstitution.

RADIATION DOSIMETRY: The radiation dose 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 Dose from Tc99m Sestamibi |
|-----------------------------|-----------------|-----------------|
| Estimated Radiation Absorbed Dose | 2.0 hour void | 4.8 hour void |
|                               | 30mCi | 1110MBq | 30mCi | 1110MBq |
| Radiation dose (rad) | 1.5 | 1.5 | 2.0 | 2.0 |
| Radiation dose (mGy) | 0.2 | 0.2 | 0.3 | 0.3 |
| Radiation dose (Gy) | 0.2 | 0.2 | 0.3 | 0.3 |
| Radiation dose (Sv) | 0.2 | 0.2 | 0.3 | 0.3 |

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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.

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Nuclear Medicine Management System

A revolutionary new application for nuclear medicine computers has been introduced by ADAC Laboratories. The PIIMS™ was first demonstrated at the 1992 Society of Nuclear Medicine Meeting. Benefits to the department user include improved department quality via better information management; increased efficiency from streamlined workflow and improved communications; monitoring or performance and reimbursement parameters and reduced work effort due to increased department organization. The PIIMS™ expands ADAC’s PEGASYS™ system making it the most comprehensive nuclear medicine workstation by adding information management features. The design is based on advanced relational database software and allows the user to configure the system to meet the ever-changing department’s needs. ADAC Laboratories, 540 Alder Dr., Milpitas, CA 95035.

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Syringe Shield

Biodex Medical Systems has improved the design of their most popular syringe shield by making it quicker and easier to use. The shield now features a white, coated interior to enhance the print on syringes for quick legible viewing. The new spring clamp feature allows broken glass to be replaced in seconds by simply sliding a new piece through the grooved clamp. The syringe shields are lightweight and pencil-thin for easy manipulation of shield and syringe combination. Constructed of a special tungsten alloy, protection is greater than an equivalent amount of lead. Biodex Medical Systems, Inc., Box 782, Shirley, NY 11967-0792.

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