YOUR DOCTOR HAS ORDERED A STRESS TEST WITH

Cardiolite®

A Patient Guide to Help Answer Your Questions About the Test

Lantheus Medical Imaging provided this booklet as a service to your doctor. Your doctor has directed you to our website to help you understand this test. The booklet does not provide complete information about your stress test or Cardiolite®. It cannot replace talking with your doctor about the test. If you have questions after reading this booklet, discuss them with your doctor.

Please See Important Safety Information and Full Prescribing Information for Cardiolite® at the back of this booklet.
What is a stress test?

A stress test is used by doctors to diagnose heart disease. If your doctor wants you to have a stress test, you may have symptoms of heart disease or certain risk factors for it. Not everyone who has a stress test has heart disease. Your test results can help your doctor determine if you have disease or if you may be at risk for a heart attack.

What is Cardiolite®?

Cardiolite® is an imaging agent used in stress tests to see how well blood is flowing to and through your heart. If you have a stress test with Cardiolite®, your doctor will inject you with a small amount of radioactive Cardiolite® and use a special camera to take pictures of your heart. Please discuss any concerns regarding this procedure with your doctor.

Why does my doctor want me to have this test?

There are several reasons you may be asked to have a stress test with Cardiolite®:

**YOUR DOCTOR SUSPECTS YOU MAY HAVE HEART DISEASE AND WANTS TO CONFIRM IT.** Your doctor may suspect coronary artery disease if you have chest pressure or other symptoms. Having certain risk factors such as high blood pressure or family history of heart disease could also increase your chance of having coronary artery disease. It’s important to be tested, because some people with heart disease feel no symptoms at all.

**YOUR DOCTOR ALREADY KNOWS YOU HAVE HEART DISEASE AND WANTS TO MONITOR YOUR CONDITION.** If you have already been diagnosed with heart disease, your doctor may ask for a stress test to:

- Look for any heart damage you may have
- Track the progress of your condition and assess your risk for problems in the future
- Determine how well your treatment is working

A stress test with Cardiolite® provides information about how well blood is flowing to your heart and how well your heart is working.
How does the test work?
A test with Cardiolite® usually consists of taking pictures of your heart in two phases: a stress phase and a resting phase.

Where are stress tests given?
Stress tests are given in special offices called nuclear medicine or nuclear cardiology labs. The labs may be in hospitals or in outpatient offices.

Who performs stress tests?
Stress tests are performed by healthcare providers specially trained to give them. Your test may be given by a qualified healthcare provider such as a doctor, nurse, or technologist.

How long will the test take?
Stress tests may be completed in 1 day or on 2 separate days. Normally, the test takes 2 to 4 hours to complete. If your test is done on 2 separate days, it will take about 2 hours each day.

How should I prepare for the test?
Follow your doctor’s advice when preparing for the test. He or she may tell you:

- Not to eat or drink for several hours before the test. Patients with diabetes may receive special orders.
- Not to take some of your medicines before the test. Your doctor will tell you which ones not to take.
- To avoid caffeine for 24 hours before the test. Caffeine may affect your results. When you make your appointment, the staff at the lab may offer even more advice. For example, they may tell you to:
  - Bring a list of all your medicines with you. The staff will ask you to name all the medicines you take, even the ones you may not be taking on that day.
  - Wear loose, comfortable clothing for the exercise phase of the test. Wear footwear with non-skid soles, too.
  - You may be asked to exercise as hard as you can, and these items may increase your comfort.
What will happen during the stress phase of the test?

A stress test is used by your doctor to determine whether or not you have heart disease. Your stress test may contain two phases, a resting phase and a stress phase. Your doctor will inform you of the order of the phases. To begin, the staff will place a small IV line in your arm. During the test you will be injected with medicine through this IV line. You may also have small pads (known as electrocardiogram or ECG electrodes) attached to your body. The pads will allow the staff to monitor your heart rate.

The stress phase of the test depends on the type of stress used:

**IF YOU ARE ABLE TO EXERCISE:**
You will exercise on a treadmill or bicycle. When you reach your peak exercise level, you will be injected with Cardiolite®. The Cardiolite® will travel through your bloodstream to your heart. Speak up right away if you become short of breath, feel pain in your arm or chest, or get tired at any time during the test.

**IF YOU ARE UNABLE TO EXERCISE:**
You will be given medicine through the IV line. This medicine will affect your heart in a way that is similar to exercise. You will also be injected with Cardiolite®. The Cardiolite® will travel through your bloodstream to your heart. Speak up right away if you become short of breath, feel pain in your chest, or feel any other symptoms at any time during the test.

Whether your stress is from exercise or a drug, the last part of the stress phase is the same. You will either be lying down on a table or sitting in a chair while a type of camera called a gamma camera takes images of your heart.

The camera “sees” the Cardiolite® in your heart and uses it to help create the pictures of your heart.

What will happen during the resting phase of the test?

The resting phase may occur before or after the stress phase, as determined by your doctor. Cardiolite® will be injected while you are resting. After that, more pictures will be taken. This set of pictures will show the flow of blood through your heart at rest.

How will I receive my test results?

The doctor at the lab will compare your two sets of pictures and send a report to your doctor. Your doctor will then discuss the results with you.
IMPORTANT SAFETY INFORMATION: Cardiolite® and Miraluma® are different names for the same drug. Inform your healthcare provider if you have had an allergic reaction to either drug or if you have had an imaging study with either drug. Exercise and pharmacologic stress testing should be performed only under the supervision of a qualified doctor. On rare occasions, a very small number of people who are given Cardiolite® have serious allergic side effects, including skin rashes. The most common complaints include headache, chest pain, nausea, and abnormal taste and smell. There may also be some side effects that only the doctor will notice while your heart is being monitored. If you are pregnant, suspect you may be pregnant, or are a nursing mother, discuss this with your doctor before undergoing the procedure.

If your doctor has decided to use a special drug to cause stress, instead of exercise activity, be sure to discuss your diet and other medicines prior to receiving the drug. It is important that your doctor know all medicines that you are taking. This includes any prescription medicines, over-the-counter drugs, or dietary supplements.

INDICATIONS AND USAGE: Cardiolite®, Kit for the Preparation of Technetium Tc99m Sestamibi for Injection, is a myocardial perfusion agent that is indicated for detecting coronary artery disease by localizing myocardial ischemia (reversible defects) and infarction (non-reversible defects), in evaluating myocardial function and developing information for use in patient management decisions. Cardiolite® evaluation of myocardial ischemia can be accomplished with rest and cardiovascular stress techniques (eg, exercise or pharmacologic stress in accordance with the pharmacologic stress agent’s labeling). It is usually not possible to determine the age of a myocardial infarction or to differentiate a recent myocardial infarction from ischemia.

CARDIOLITE®
Kit for the Preparation of Technetium Tc99m Sestamibi for Injection

FOR DIAGNOSTIC USE IN SPECIFIC PATIENTS

INDICATIONS AND USAGE
CARDIOLITE® is a myocardial perfusion agent indicated for:

• detecting coronary artery disease by localizing myocardial ischemia (reversible defects) and infarction (non-reversible defects)
• evaluating myocardial function and developing information for use in patient management decisions

DOSEAGE AND ADMINISTRATION

For Myocardial Imaging: The suggested dose range for I.V. administration of CARDIOLITE® in a single dose to be employed in the average patient (70 Kg) is 370 - 1110 MBq (10 - 30 mCi).

For Breast Imaging: The recommended dose range for I.V. administration of MIRALIMA® is a single dose of 740 - 1110 MBq (20 - 30 mCi).

DOSE AND STRENGTHS

For Myocardial Imaging: CARDIOLITE® Kit for the Preparation of Technetium Tc99m Sestamibi for Injection is supplied as a lyophilized mixture in a 5 ml vial.

CONTRAINDICATIONS

None known

WARNING AND PRECAUTIONS

Pharmacologic induction of cardiovascular stress may be associated with serious adverse events such as myocardial infarction, arrhythmia, hypotension, chest pain, chest discomfort and cerebrovascular events.

CARDIOLITE® has been rarely associated with severe allergic and anaphylactic events of angioedema and generalized urticaria. In some patients the allergic symptoms developed on the second injection during CARDIOLITE® imaging.

Caution should be exercised and emergency equipment should be available when administering CARDIOLITE®

Before administering CARDIOLITE®, patients should be asked about the possibility of allergic reactions to either drug.

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 preparative procedure.

ADVERSE REACTIONS

The following adverse reactions have been reported in < 0.5% of patients: signs and symptoms consistent with those occurring shortly after administration of the agent; transient arthritis, angioedema, arthralgia, dizziness, syncope, abdominal pain, vomiting, and severe hypersensitivity characterized by dyspnea, hypotension, bronchospasm, angioneurotic edema, and flushing within two hours after a second injection of Technetium Tc99m Sestamibi. A few cases of flushing, edema, injection site inflammation, dyspnea, fever, pruritis, rash, urticaria and fatigue have also been attributed to administration of the agent.

To report SUSPECTED ADVERSE REACTIONS, contact Lantheus Medical Imaging, Inc. at 1-800-362-2668 or FDA at 1-800-FDA-1088 or 17. PATIENT COUNSELING INFORMATION

DRUG INTERACTIONS

Specific drug-drug interactions have not been studied.

USE IN SPECIFIC POPULATIONS

In one study of 46 subjects who received CARDIOLITE® injection of Technetium Tc99m Sestamibi. A few cases of flushing, edema, hypotension, bradycardia, asthenia, and vomiting within two hours after a second administration, the administration of CARDIOLITE® was associated with an increase in blood pressure and heart rate.

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STRESS

<table>
<thead>
<tr>
<th>STRESS</th>
<th>2.0 hour void</th>
<th>4.8 hour void</th>
</tr>
</thead>
<tbody>
<tr>
<td>Organ</td>
<td>30 mCi</td>
<td>1110 MBq</td>
</tr>
<tr>
<td>Breasts</td>
<td>0.2 - 2.0</td>
<td>0.2 - 1.9</td>
</tr>
<tr>
<td>Gallbladder Wall</td>
<td>2.0 - 20.0</td>
<td>2.0 - 20.0</td>
</tr>
<tr>
<td>Small Intestine</td>
<td>3.0 - 30.0</td>
<td>3.0 - 30.0</td>
</tr>
<tr>
<td>Upper Large Intestine Wall</td>
<td>5.4 - 55.5</td>
<td>5.4 - 55.5</td>
</tr>
<tr>
<td>Lower Large Intestine Wall</td>
<td>3.9 - 40.0</td>
<td>4.2 - 41.1</td>
</tr>
<tr>
<td>Stomach Wall</td>
<td>0.6 - 6.1</td>
<td>0.6 - 5.8</td>
</tr>
<tr>
<td>Heart Wall</td>
<td>0.5 - 5.1</td>
<td>0.5 - 4.9</td>
</tr>
<tr>
<td>Kidneys</td>
<td>2.0 - 20.0</td>
<td>2.0 - 20.0</td>
</tr>
<tr>
<td>Liver</td>
<td>0.6 - 5.8</td>
<td>0.6 - 5.7</td>
</tr>
<tr>
<td>Lungs</td>
<td>0.3 - 2.7</td>
<td>0.3 - 2.7</td>
</tr>
<tr>
<td>Bone Surfaces</td>
<td>0.7 - 6.4</td>
<td>0.7 - 6.4</td>
</tr>
<tr>
<td>Thyroid</td>
<td>0.7 - 7.0</td>
<td>0.7 - 7.0</td>
</tr>
<tr>
<td>Ovaries</td>
<td>1.5 - 15.5</td>
<td>1.6 - 15.5</td>
</tr>
<tr>
<td>Testes</td>
<td>0.3 - 3.4</td>
<td>0.4 - 3.9</td>
</tr>
<tr>
<td>Red Marrow</td>
<td>0.5 - 5.0</td>
<td>0.5 - 5.0</td>
</tr>
<tr>
<td>Urinary Bladder Wall</td>
<td>2.0 - 20.0</td>
<td>2.0 - 41.1</td>
</tr>
<tr>
<td>Total Body</td>
<td>0.5 - 4.8</td>
<td>0.5 - 4.8</td>
</tr>
</tbody>
</table>

Table 1.0.  Radiation Absorbed Doses from Tc99m Sestamibi

Estimated Radiation Absorbed Dose

Table 1.0. Radiation Absorbed Doses from Tc99m Sestamibi
Breast Studies

Radioisotopes must be handled with care and appropriate safety measures first undergoing the preparative procedure.

The most frequent exercise stress test endpoints sufficient to stop the test reported during controlled studies (two-thirds were cardiac patients) were:

- Fatigue 35%
- Dyspnea 17%
- Chest Pain 16%
- T-Depression 12%
- Arthritia 1%

6. ADVERSE REACTIONS

Adverse events were evaluated in 3741 adults who were evaluated in clinical studies. Of these patients, 3068 (77% men, 22% women, and 0.7% of the patient’s gender were not recorded) were in cardiac clinical trials and 673 (100%) women were in breast imaging trials. Cases of angina, chest pain, and death have occurred (see Section 5). Adverse events reported at a rate of 0.5% or greater after receiving Technetium Tc99m Sestamibi administration are shown in the following tables.

Table 2.0

<table>
<thead>
<tr>
<th>Table 2.0 Selected Adverse Events Reported in &gt; 0.5% of Patients Who Received Technetium Tc99m Sestamibi in Either Breast or Cardiac Clinical Studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Body System</td>
</tr>
<tr>
<td>---------------</td>
</tr>
<tr>
<td>Body as a Whole</td>
</tr>
<tr>
<td>Head</td>
</tr>
<tr>
<td>Cardiac</td>
</tr>
<tr>
<td>Cardiac Pain/Angina</td>
</tr>
<tr>
<td>ST segment changes</td>
</tr>
<tr>
<td>Digestive System</td>
</tr>
<tr>
<td>Special Sensibilities</td>
</tr>
<tr>
<td>Taste Perversion</td>
</tr>
<tr>
<td>Paralysis</td>
</tr>
<tr>
<td>Excludes 22 patients whose gender was not recorded</td>
</tr>
</tbody>
</table>

In the clinical studies for breast imaging, breast pain was reported in 12 (1.7%) of the patients. In 11 of these patients the pain appears to be associated with biopsy/surgical procedures.

The following adverse reactions have been reported in > 0.5% of patients: signs and symptoms consistent with severe occurring shortly after administration of the agent, transIsotretin, angioedema, urticaria, dyspnea, bronchoconstriction and cerebrovascular events. Caution should be used when pharmacologic stress is selected as an alternative to exercise; it should be used when indicated and in accordance with the pharmacologic stress agent's labeling.

Technetium Tc99m Sestamibi is rarely associated with acute severe allergic and anaphylactic events of angioedema and generalized urticaria. In some patients the allergic symptoms developed on the second injection during CARDIOLITE® imaging. Patients who receive CARDIOLITE® or MIRALUMA® imaging are receiving the same drug. Caution should be exercised and emergency equipment should be available when administering Technetium Tc99m Sestamibi. Also, before administering either CARDIOLITE® or MIRALUMA®, patients should be asked about the possibility of allergic reactions to other drug.

5.2 General Precautions

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 the preparative procedure.

Radiative drugs must be handled with care and appropriate safety measures should be used to minimize radiation exposure to clinical personnel. Also, care must be taken to minimize radiation exposure to the patients consistent with professional 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 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.

In a clinical pharmacology study, 46 pediatric patients with Kawasaki disease received CARDIOLITE® administration at the following doses: 0.1 - 0.2 mCi/kg for rest, 0.3 mCi/kg for stress in one study days; 0.2 mCi/kg for rest and 0.2 mCi/kg for stress in two day studies. The radioactivity both in younger children and in adolescents exhibited PK profiles similar to those previously reported in adults (See Section 12).

The radiation absorbed doses in adolescents, both at rest and stress, were similar to those observed in adults (See Section 2). When comparing weight-adjusted radioactivity (up to 0.3 mCi/kg) doses administered to adolescents and younger children to the recommended dose administered to adults (up to 0.3 mCi/kg), the radiation absorbed doses in both adolescents and younger children were similar to those in adults.

Adverse events were evaluated in 609 pediatric patients from the three clinical studies described above. The frequency and the type of the adverse events were similar to the ones observed in the studies of CARDIOLITE® in adults. Two of the 609 had a serious adverse event: one patient received a CARDIOLITE® overdose but remained asymptomatic, and one patient had an asthma exacerbation following administration.

6.5 Geriatric Use

Of 3068 patients in clinical studies of CARDIOLITE®, Kit for the Preparation of Technetium Tc99m Sestamibi for Injection, 693 patients were 65 or older and 121 were 75 or older.

Of 673 patients in clinical studies of MIRALUMA®, Kit for the Preparation of Technetium Tc99m Sestamibi for Injection, 138 patients were 65 or older and 30 were 75 or older.

Based on the evaluation of the frequency of adverse events and review of vital signs data, no overall differences in safety were observed between these subjects and younger subjects. Although reported clinical experience has not identified differences in response between elderly and younger patients, greater sensitivity of some older individuals cannot be ruled out.

6.6 Pregnancy

Each 5 mL vial contains a sterile, non-pyrogenic, lyophilized mixture of:

- Tetras (2-methoxy isobutyl isonitrile) Copper (I) tetrafluoroborate - 1.0 mg
- Sodium Citrate Dihydrate - 2.6 mg
- L-Cystine Hydrcholoride Monohydrate - 1.0 mg
- Sodium Tetrachloroaurate - 0.025 mg
- Stannous Chloride, Dihydrate, minimum (SnCl₂·2H₂O) - 0.03 mg
- Sodium Chloride, Dihydrate, (SnCl₂·2H₂O) - 0.075 mg
- Chloride (stannous and stannic) Dihydrate, maximum (as SnCl₂) - 0.086 mg

Prior to lyophilization 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, oxygen-free Sodium Pertechnetate Tc99m Injection. The pH of the reconstituted product is 5.5 (5.0 - 6.0). No bacteriostatic preservative is present.

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

11.1 Physical Characteristics

Technetium Tc99m decays by isomeric transition with a physical half-life of 6.02 hours². Photons that are useful for detection and imaging studies are listed below in Table 3.0.

Table 3.0. Principal Radiation Emission Data

<table>
<thead>
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<th>Mean Energie (KeV)</th>
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<tbody>
<tr>
<td>Gamma Ray</td>
<td>99.99%</td>
<td>100%</td>
<td>140 KeV</td>
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Kocher, D. C., Radioactive Decay Data Tables, DOT/TC/11020, 10/1991.

11.2 External Radiation

The specific gamma ray constant for Tc99m is 5.4 microccmoulbs/Mg-Bq-hr (0.798 mCi-hr/Mg) at 1 cm. The first half value layer is 0.017 cm from MIBI. A range of values for the relative attenuation of the radiation emitted by this radionuclide (0.78R/mCi-hr) at 1 cm. The first half value layer is 0.017 cm of Pb. A range of values for the relative attenuation of the radiation emitted by this radionuclide (0.78R/mCi-hr) at 1 cm. The first half value layer is 0.017 cm of Pb.

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</tbody>
</table>
32(27,37)
16(13,19)
48 (19%)
11 (44%)
14 (56%)
52 (79%)
®
80(75,85)
®
13 (41%)
95 (83%)

relationship of normal or abnormal perfusion scans and long term cardiac events was
found (79,81). In an individual patient, however, the intensity of MIRALUMA® uptake
can not be used to confirm the presence or absence of malignancy. Equivalor results do not have a correlation with histology.

An estimate of the likelihood of malignancy based on the MIRALUMA® uptake score in combination with the mammographic score has not been studied. In these two studies approximately 150 additional, non-biopsied lesions were found to be positive after MIRALUMA® imaging. These lesions were identified in sites that did not physiologically correlate with identified entry criteria mammographic lesions and these lesions were not palpable. These lesions were not biopsied. When these lesions were benign or malignant, the MIRALUMA® uptake can occur in both benign and malignant disease. The CLINICAL USEFULNESS OF A POSITIVE MIRALUMA® IMAGE IN THE ABSENCE OF AN ABNORMAL MAMMGRAM OR AN ABNORMAL LESION IS NOT KNOWN.

15. REFERENCES
Not applicable.

16. HOW SUPPLIED/STORAGE AND HANDLING
CARDIOLITE®, Kit for the Preparation of Technetium Tc99m Sestamibi for Injection is supplied as a 5 mL vial in kits of five (5) vials (NDC #11994-001-55) and twenty (20) vials (NDC #11994-001-20), sterile and non-pyrogenic.

The patient dose should be measured by a suitably radiotracivity 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.

Prior to lyophilization the pH is between 5.3-5.9. The contents of the vial are sterilized and stored under nitrogen. Store at 15-25°C (59-77°F) before and after reconstitution.

Tellurium Tc99m Sestamibi contains no preservatives. Included in each five (5) vial kit is one (1) package insert, six (6) vial labels and six (6) radiation warning labels. Included in each twenty (20) vial kit is one (1) package insert, twenty four (24) vial strip labels and twenty four (24) radiation warning labels.  This reagent kit is approved for distribution to persons licensed pursuant to the Code of Massachusetts Regulations 105 CMR 120.500 for the uses listed in 105 CMR 120.547 or 120.552, or under equivalent regulations of the U.S. Nuclear Regulatory Commission, Agreement States or Licensing States.

17. PATIENT COUNSELING INFORMATION
CARDIOLITE® and MIRALUMA® are different names for the same drug. Patients should be advised to inform their health care provider if they had an allergic reaction to either drug or if they had an imaging study with either drug.