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Cardiolite®
Kit for the preparation of Technetium Tc99m Sestamibi

To reduce soft-tissue attenuation
Cardiolite comes through

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Animal reproduction and teratology 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 reports of studies in pregnant women. Technetium Tc99m Sestamibi should be given to a pregnant woman only if clearly needed.

Pregnancy Category C

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-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 following adverse reactions have been rarely reported: signs and symptoms consistent with severe exposure occurring shortly after administration of the agent; transient; and severe in the worst part: hyperventilation, which was characterized by dyspnea, hypotension, bradycardia, and vomiting within two hours after a second injection of Technetium Tc99m Sestamibi.

DOSAGE AND ADMINISTRATION: The suggested dose range for I.V. administration is 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 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 container permit.

RADIATION DOSEIMETRY: 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>REST</th>
<th>STRESS</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>2.0 hour void</td>
<td>4.8 hour void</td>
</tr>
<tr>
<td></td>
<td>30mCi</td>
<td>mGy/MBq</td>
</tr>
<tr>
<td>Breasts</td>
<td>0.2</td>
<td>1.9</td>
</tr>
<tr>
<td>Gallbladder Wall</td>
<td>2.0</td>
<td>2.0</td>
</tr>
<tr>
<td>Small Intestine</td>
<td>3.0</td>
<td>3.0</td>
</tr>
<tr>
<td>Upper Large Intestine Wall</td>
<td>5.4</td>
<td>5.4</td>
</tr>
<tr>
<td>Lower Large Intestine Wall</td>
<td>4.0</td>
<td>4.2</td>
</tr>
<tr>
<td>Stomach Wall</td>
<td>0.6</td>
<td>0.6</td>
</tr>
<tr>
<td>Heart Wall</td>
<td>0.7</td>
<td>0.7</td>
</tr>
<tr>
<td>Kidneys</td>
<td>2.0</td>
<td>2.0</td>
</tr>
<tr>
<td>Liver</td>
<td>0.6</td>
<td>0.6</td>
</tr>
<tr>
<td>Bone Surfaces</td>
<td>0.7</td>
<td>0.7</td>
</tr>
<tr>
<td>Thyroid</td>
<td>1.5</td>
<td>1.6</td>
</tr>
<tr>
<td>Ovaries</td>
<td>0.5</td>
<td>0.5</td>
</tr>
<tr>
<td>Red Marrow</td>
<td>0.5</td>
<td>0.5</td>
</tr>
<tr>
<td>Urinary Bladder Wall</td>
<td>0.5</td>
<td>0.5</td>
</tr>
<tr>
<td>Total Body</td>
<td>0.5</td>
<td>0.5</td>
</tr>
</tbody>
</table>

Radiopharmaceutical Internal Dose Information Center, July 1990, Oak Ridge Associated Universities, P.O. Box 173, Oak Ridge, TN 37830, 615-576-3448.

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

Prior to administration, the pH should be between 5.3-5.9. The contents of the vials are hypodermised and stored under nitrogen.

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

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.

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Section of Nuclear Medicine

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<tr>
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<th>CRT Monitor</th>
<th>HR/R-R Int</th>
<th>Trigger</th>
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