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

FOR DIAGNOSTIC USE

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

Tc99m-B001 May 2003

Physical characteristics: Technetium Tc99m Sestamibi is a cationic Tc99m complex which has been found to accumulate in a number of locations in the body, such as the myocardium, liver, and lungs. It is used in diagnostic imaging to detect and localize abnormal tissue, particularly in the heart. The 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 solution is 5.3 to 5.5. It is stored under refrigeration until use.

PHYSICAL CHARACTERISTICS

Radiation

Gamma -2 89.07 140.5

Table 3. Physical Decay Chart; Tc99m Half-Life 6.02 Hours

Table 1. Intradose宣 depressive by isometry with a partial high lab of 6.02 hours. Photons that are useful for detection and imaging studies are listed in Table 1.

Table 2. Radiation Emission Data

<table>
<thead>
<tr>
<th>Mean % Disintegration</th>
<th>Gamma Energy (MeV)</th>
</tr>
</thead>
<tbody>
<tr>
<td>90.0%</td>
<td>140.5</td>
</tr>
</tbody>
</table>

To correct for physical decay of this radionuclide, the fractions that remain at selected intervals after the time of calibration are shown in Table 3.

Table 2. Radiation Attenuation by Lead Shielding

<table>
<thead>
<tr>
<th>Radiation</th>
<th>Lead Thickness (cm)</th>
<th>Attenuation</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.07</td>
<td>0.08</td>
<td>0.09</td>
</tr>
<tr>
<td>0.11</td>
<td>0.12</td>
<td>0.13</td>
</tr>
<tr>
<td>0.16</td>
<td>0.17</td>
<td>0.18</td>
</tr>
</tbody>
</table>

In studying patients in whom cardiac disease is known or suspected, care should be taken to assure continuous monitoring and treatment in accordance with accepted clinical procedure. Infrequently, death has occurred 4 to 24 hours after Technetium Tc99m Sestamibi use and it is usually associated with recurrent cardiovascular testing.

MIRALUMA® is not indicated for breast cancer screening, to confirm the presence or absence of malignancy, and it is not to alterative to biopsy.

CONTRASTING:

None known.

MEDICINE:

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PRECAUTIONS:

None known.

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 sufficient to stop the test reported during controlled studies (two-thirds were fatigue) were:

Fatigue 35%
Dyspnea 17%
Cheek Pain 16%
Increased BP 7%
Antipyretic 1%
The following adverse reactions have been reported in
In 11 of these patients the pain appears to be associated with biopsy/surgical procedures. In the clinical studies for breast imaging, breast pain was reported in 12 (1.7%) of the patients.

For Myocardial Imaging: The suggested dose range for I.V. administration of CARDIOLITE® in a single

Inflammation, dry mouth, fever, pruritus, rash, urticaria and fatigue have also been attributed to

It is recommended that images are obtained with a table overlay to separate breast

Based on the evaluation of the frequency of adverse events and review of vital signs data, no overall differences in safety were observed between breast and cardiac 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.

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 patients’ genders were not recorded) were in cardiac

Total Body 0.4 4.2 0.4 4.2

The active intermediate, Cu(MIBI)4BF4, was evaluated for genotoxic potential in a battery of five tests.

KIDNEYS

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Total Body 0.5 4.8 0.5 4.8

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