KIT FOR THE PREPARATION OF TECHNETIUM Tc 99m SESTAMIBI INJECTION

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use this kit for the Preparation of Technetium Tc 99m Sestamibi Injection. Consult the full prescribing information before using this kit for the Preparation of Technetium Tc 99m Sestamibi Injection. See black box warning.

Indications and Usage

Technetium Tc 99m Sestamibi is a myocardial perfusion imaging agent that is indicated for:

1. Myocardial perfusion imaging in patients with angina pectoris and/or cardiomegaly or cardiac enzyme abnormalities to help evaluate the presence of coronary artery disease

2. Imaging of cardiac lesions in patients with an abnormal mammogram

Dosage and Administration

2.1 Image Acquisition

The recommended dose range for 120 minute SPECT or planar imaging in patients with an abnormal mammogram is 10 mCi (0.37 GBq) to 30 mCi (1.11 GBq). For patients with a high risk of breast cancer, 30 mCi (1.11 GBq) or more may be appropriate.

2.2 Intravenous Administration

The product should be used within 6 hours after reconstitution.

Contraindications

1. Hypersensitivity to Technetium Tc 99m Sestamibi or any components of this product

Warnings and Precautions

5.2 General Warnings

The contents of the vial should be used only for one use in a single patient. The vial should not be reused or reconstituted. See Warnings and Precautions (5.3) for additional information.

5.3 Adverse Reactions

Adverse reactions following Technetium Tc 99m Sestamibi administration are shown in the table below:

<table>
<thead>
<tr>
<th>Organ</th>
<th>30 mCi</th>
<th>1110 MBq</th>
<th>30 mCi</th>
<th>1110 MBq</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breasts</td>
<td>0.2</td>
<td>2.0</td>
<td>0.2</td>
<td>1.8</td>
</tr>
<tr>
<td>Lungs</td>
<td>0.3</td>
<td>2.6</td>
<td>0.2</td>
<td>2.4</td>
</tr>
<tr>
<td>Liver</td>
<td>0.6</td>
<td>5.8</td>
<td>0.6</td>
<td>5.7</td>
</tr>
<tr>
<td>Small Intestine</td>
<td>2.4</td>
<td>24.4</td>
<td>2.4</td>
<td>24.4</td>
</tr>
<tr>
<td>Intestine Wall</td>
<td>3.9</td>
<td>40.0</td>
<td>4.2</td>
<td>41.1</td>
</tr>
<tr>
<td>Kidneys</td>
<td>0.7</td>
<td>6.7</td>
<td>0.9</td>
<td>7.7</td>
</tr>
<tr>
<td>Cardiac</td>
<td>3.9</td>
<td>13.0</td>
<td>3.9</td>
<td>13.0</td>
</tr>
<tr>
<td>Skin</td>
<td>3.5</td>
<td>8.7</td>
<td>3.5</td>
<td>8.7</td>
</tr>
<tr>
<td>Nervous</td>
<td>0.6</td>
<td>2.3</td>
<td>0.5</td>
<td>2.1</td>
</tr>
<tr>
<td>Other</td>
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Adverse reactions were evaluated in 3741 adults who received Technetium Tc 99m Sestamibi. The most frequent exercise stress test endpoints associated with Technetium Tc 99m Sestamibi were chest pain (16%) and fatigue (35%).

Radiation dosimetry calculations performed by Radiation Dose Information Center, Oak Ridge National Laboratory, for SCAT 180 and SCAT 117. Oak Ridge National Laboratory, 2000 Y-12 RD-166-2C.

Full prescribing information is available at the following website: www.accessdata.fda.gov/drugsatfda_docs/label/2018/300591s015lbl.pdf

A09213 R1/2018

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092

For the Prevention of Technetium Tc 99m Sestamibi Injection

2.1 Image Acquisition

Surgical procedures:

1. Technique:

a. The patient is brought into the imaging department and is placed on the table, head first, side by side with the technologist. The table is slowly raised, and then lowered, until the top of the head is 1 inch below the horizontal plane. The patient is asked to look downward at each end of the procedure.

b. Before imaging, the hands are washed and dried with alcohol to sanitize the surface.

c. For simple studies, use of gloves is optional.

2. Dosage and Administration

Technetium Tc 99m Sestamibi is not indicated for use in patients with a history of anaphylaxis, malaise, and it is not in vitro to extensive transcutaneous detection.

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The product should be used within 6 hours after reconstitution.

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b. Before imaging, the hands are washed and dried with alcohol to sanitize the surface.

c. For simple studies, use of gloves is optional.

2. Dosage and Administration

Technetium Tc 99m Sestamibi is not indicated for use in patients with a history of anaphylaxis, malaise, and it is not in vitro to extensive transcutaneous detection.
The following adverse reactions have been reported in a study of 200 patients scanned with Technetium Tc 99m Sestamibi. Reactions were reported as occurring either during or immediately after (up to 120 minutes after) injection of Technetium Tc 99m Sestamibi. They included: flushing, dyspnea, cardiac palpitations, nausea, vomiting, dizziness, syncope, abdominal pain, and vomiting. Additional reactions occurred in the following time periods: 1-2 hours after injection, 2-5 days after injection, 6-14 days after injection, and after 14 days after injection. Some of these reactions may not be due to Technetium Tc 99m Sestamibi itself, but rather to the radiopharmaceutical package material used for injection.

7 DISCUSSION
Specific drug interactions have not been studied.

8 USER-SPECIFIC POPULATIONS
8.1 Pregnancy Category C

Technetium Tc 99m Sestamibi has not been studied in pregnant women. It is not known whether Technetium Tc 99m Sestamibi can cause fetal harm when administered to a pregnant woman. Therefore, formula feedings should be substituted for breast feeding.

8.2 Pediatric Use

The effects of Technetium Tc 99m Sestamibi in the pediatric population have not been established.

9 NURSING MOTHERS

Tc 99m Sestamibi has been excreted in human milk during lactation. It is not known whether Technetium Tc 99m Sestamibi is excreted into breast milk. Therefore, breast feeding should be avoided.

9.3 Radiation Information

Radioactivity from Technetium Tc 99m Sestamibi is emitted by a factor of 1,000.

Table 5

<table>
<thead>
<tr>
<th>Radiation Mean %</th>
<th>Mean Energy</th>
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</tr>
</thead>
<tbody>
<tr>
<td>5 min. 1.2 1.2</td>
<td>20.0 19.0</td>
<td>1 min. 1.1 1.1</td>
<td>17.0 16.0</td>
</tr>
<tr>
<td>3 min. 1.6 1.6</td>
<td>8.0 7.0</td>
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</tr>
</tbody>
</table>

To correct for physical decay of the radionuclide, the fractions that remain are scored intensitites after the time allowed for the physica decay to occur.

10 CLINICAL PHARMACOLOGY

1.2 General

Tc 99m Sestamibi is a copper-complexing agent that is used to provide myocardial visualization. Tc 99m Sestamibi is a high-affinity target for myocardial cells. The high-affinity myocardial uptake of Tc 99m Sestamibi is due to the presence of the high-affinity myocardial uptake of Technetium Tc 99m Sestamibi.

12.3 Metabolism

The metabolites of Technetium Tc 99m Sestamibi have not been identified. The final isotopic skeleton is a consequence of Technetium Tc 99m Sestamibi uptake in the anatomic region of interest. The final isotopic skeleton is a consequence of injection of Technetium Tc 99m Sestamibi. The final isotopic skeleton is a consequence of Technetium Tc 99m Sestamibi uptake in the anatomic region of interest. The final isotopic skeleton is a consequence of injection of Technetium Tc 99m Sestamibi. The final isotopic skeleton is a consequence of Technetium Tc 99m Sestamibi uptake in the anatomic region of interest. The final isotopic skeleton is a consequence of injection of Technetium Tc 99m Sestamibi. The final isotopic skeleton is a consequence of injection of Technetium Tc 99m Sestamibi. The final isotopic skeleton is a consequence of injection of Technetium Tc 99m Sestamibi. The final isotopic skeleton is a consequence of injection of Technetium Tc 99m Sestamibi.

14.3 DESIGNATION

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Table 6

<table>
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<tr>
<th>Lesions* (Study A)</th>
<th>Lesions* (Study B)</th>
</tr>
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<tr>
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<td>Equivocal 10 (8%) 6 (5%)</td>
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</table>

In these studies approximately 150 additional, the normal Technetium Tc 99m Sestamibi images were reviewed. The findings were identified as normal or did not include identification with malignant and non-malignant lesions. The findings were identified as normal or did not include identification with malignant and non-malignant lesions. The findings were identified as normal or did not include identification with malignant and non-malignant lesions. The findings were identified as normal or did not include identification with malignant and non-malignant lesions.

15 REFERENCES

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16 USEFUL DRUG INTERACTIONS

Folate deficiency and drug interactions with folic acid antagonists that commonly do not cause significant systemic toxicity (toxicity limited to the gastrointestinal tract) can cause folate deficiency and drug interactions with folic acid antagonists that commonly do not cause significant systemic toxicity (toxicity limited to the gastrointestinal tract). Folate deficiency and drug interactions with folic acid antagonists that commonly do not cause significant systemic toxicity (toxicity limited to the gastrointestinal tract). Folate deficiency and drug interactions with folic acid antagonists that commonly do not cause significant systemic toxicity (toxicity limited to the gastrointestinal tract).

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17 HOW SUPPLIED/STORAGE AND HANDLING

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Curium, MIBI and MIBG are different names for the drug with the same Chemical Abstracts Service Numbers as Technetium Tc 99m Sestamibi (Parent Drug). Curium, MIBI and MIBG are different names for the drug with the same Chemical Abstracts Service Numbers as Technetium Tc 99m Sestamibi (Parent Drug). Curium, MIBI and MIBG are different names for the drug with the same Chemical Abstracts Service Numbers as Technetium Tc 99m Sestamibi (Parent Drug).

Manufactured by LILAC Medical Imaging, Inc.

2002

Distributed by LILAC Medical Imaging, Inc.

US Patent D293,218

As shown in Table 8 and 9, the majority of the Technetium Tc 99m Sestamibi images were reviewed. The findings were identified as normal or did not include identification with malignant and non-malignant lesions (78.8%). In an individual patient, however, the in vivo clinical use of Technetium Tc 99m Sestamibi update to indicate abnormality cannot be ruled out. Technetium Tc 99m Sestamibi update to indicate abnormality cannot be ruled out. Technetium Tc 99m Sestamibi update to indicate abnormality cannot be ruled out. Technetium Tc 99m Sestamibi update to indicate abnormality cannot be ruled out.

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