For complete study, sets of images should be obtained five minutes after the injection, and in the second injection during Tc 99m Sestamibi imaging. The contents of the chest and abdomen are shielded while administering the agent to the patient. Anterior images, shield the chest and abdominal organs, and posterior images shield the legs. For lateral images, position the patient prone with the breast (for lateral images) and abdominal organs (for posterior images) shielded. The breast should not be compressed on the flat against the table, head turned to the side and relaxed, with slight pressure to avoid oropharyngeal distention. The chest should not be compressed on the flat against the table, head turned to the side and relaxed, with slight pressure to avoid oropharyngeal distention.

2.4 Determination of Radiochemical Purity in the Final Product

Radiochemical purity is determined by high performance liquid chromatography (HPLC) or thin-layer chromatography (TLC). The potential for cracking and significant radioactivity loss is diminished by the use of a preheating step in the kit preparation procedure. Remove the plastic disc and immediately autoclave the contents of the vial. After returning to room temperature, wait 10 minutes before handling.

3.2 Pharmacokinetics

The estimated radiation absorbed dose is approximately 140 mGy (14 mrad) for a 70 kg average patient (70 Kg) per 1110 MBq (30 mCi) of Technetium Tc 99m Sestamibi. Also, the contents of the vial are intended only for use in the preparation of Technetium Tc 99m Sestamibi and are not to be administered directly to the patient without undergoing the preparation procedure described in the Kit for the Preparation of Technetium Tc 99m Sestamibi Injection.

5.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

There are no reports available of carcinogenicity in studies of Technetium Tc 99m Sestamibi in animals. Also, there have been no reports of mutagenicity in the Salmonella assay. The effect of Technetium Tc 99m Sestamibi on fertility has not been studied.

6 ADVERSE REACTIONS

The most frequent exercise stress test endpoints evaluated were ischemic changes (e.g., angina, ST-segment depression, and/or T-wave changes) and the occurrence of significant LV hypertrophy as detected by echocardiography or ventriculography in the absence of clinical evidence of ischemic heart disease. The most frequent exercise stress test endpoints evaluated were ischemic changes (e.g., angina, ST-segment depression, and/or T-wave changes) and the occurrence of significant LV hypertrophy as detected by echocardiography or ventriculography in the absence of clinical evidence of ischemic heart disease. The most frequent exercise stress test endpoints evaluated were ischemic changes (e.g., angina, ST-segment depression, and/or T-wave changes) and the occurrence of significant LV hypertrophy as detected by echocardiography or ventriculography in the absence of clinical evidence of ischemic heart disease.

6.1 Clinical Studies

6.2 Pharmacokinetics

8.4 Pediatric Use

9.1 Controlled Substance

The kit is for use in the preparation of Technetium Tc 99m Sestamibi injection by a licensed person qualified in therapeutic radiology, or who is approved by the licensee to use by-product material identified in Warnings and Precautions (5.2) and the patient is under the supervision of a qualified physician and in a laboratory setting. In the clinical studies for breast imaging, breast pain and discomfort were also reported at a rate of 0.5% or greater after receiving Technetium Tc 99m Sestamibi. The most frequent exercise stress test endpoints evaluated were ischemic changes (e.g., angina, ST-segment depression, and/or T-wave changes) and the occurrence of significant LV hypertrophy as detected by echocardiography or ventriculography in the absence of clinical evidence of ischemic heart disease. The most frequent exercise stress test endpoints evaluated were ischemic changes (e.g., angina, ST-segment depression, and/or T-wave changes) and the occurrence of significant LV hypertrophy as detected by echocardiography or ventriculography in the absence of clinical evidence of ischemic heart disease.

5 WARNINGS AND PRECAUTIONS

5.1 Warnings

Patients who receive Technetium Tc 99m Sestamibi should be warned of the potential for serious adverse reactions prior to administration. The potential for cracking and significant radioactivity loss is diminished by the use of a preheating step in the kit preparation procedure. Remove the plastic disc and immediately autoclave the contents of the vial. After returning to room temperature, wait 10 minutes before handling.

7.5 Contraindications

Technetium Tc 99m Sestamibi should not be used in patients who are likely to be pregnant. If the use of Technetium Tc 99m Sestamibi is selected in pregnant women, the benefit of use must be considered by the physician against the potential risk of myocardial abnormality or other malformation, and it is not to be administered to a pregnant woman.

2.3 Preparation

2.4 Determination of Radiochemical Purity in the Final Product

Table 2

<table>
<thead>
<tr>
<th>Organ</th>
<th>Sestamibi Injection</th>
<th>Technetium Tc 99m Sestamibi</th>
<th>Window of Interest</th>
</tr>
</thead>
<tbody>
<tr>
<td>Red Blood Cells</td>
<td>1.0 16.2 1.4</td>
<td>0.3 16.2 0.5</td>
<td>0.3 2.2 0.4</td>
</tr>
<tr>
<td>White Blood Cells</td>
<td>0.3 0.6 0.1</td>
<td>0.3 0.6 0.1</td>
<td>0.3 0.6 0.1</td>
</tr>
<tr>
<td>Platelets</td>
<td>0.3 2.4 0.1</td>
<td>0.3 2.4 0.1</td>
<td>0.3 2.4 0.1</td>
</tr>
<tr>
<td>Whole Blood</td>
<td>2.3 2.6 2.4</td>
<td>1.5 4.3 1.9</td>
<td>1.5 4.3 1.9</td>
</tr>
<tr>
<td>Kidney</td>
<td>0.5 0.5 0.5</td>
<td>0.5 0.5 0.5</td>
<td>0.5 0.5 0.5</td>
</tr>
<tr>
<td>Liver</td>
<td>0.5 0.5 0.5</td>
<td>0.5 0.5 0.5</td>
<td>0.5 0.5 0.5</td>
</tr>
<tr>
<td>Cerebrovascular Events</td>
<td>2.3 2.6 2.4</td>
<td>1.5 4.3 1.9</td>
<td>1.5 4.3 1.9</td>
</tr>
<tr>
<td>Skin</td>
<td>0.5 0.5 0.5</td>
<td>0.5 0.5 0.5</td>
<td>0.5 0.5 0.5</td>
</tr>
</tbody>
</table>

9.2 Absence

12.2 Pharmacokinetics

Allergic reactions were noted in 10% of patients. The most frequent exercise stress test endpoints evaluated were ischemic changes (e.g., angina, ST-segment depression, and/or T-wave changes) and the occurrence of significant LV hypertrophy as detected by echocardiography or ventriculography in the absence of clinical evidence of ischemic heart disease.
When comparing weight-adjusted radioactivity (up to 259 patients with dense (heterogeneously/extremely dense) mammography in patients with breast densities or other mammographic findings), the following adverse events were observed at six months in this study. All adverse events were reported with an incidence rate above 10%, except for injection site reactions, which were not included.

8.4 Pediatric Use

3.0-5.9 MBq (0.08-0.16 mCi) per kg for children 2-11 years of age.

Tc-99m MIBI 6+ where MIBI is 2-methoxy isobutylisonitrile. This drug is administered by intravenous injection. Tin Chloride (stannous and stannic) Dihydrate, and/or hydrochloric acid may have been added to the lyophilized mixture of:

The mechanism of Tc 99m Sestamibi localization in various types of breast tissue (e.g., benign, inflammatory, metastatic) is not well understood. In general the histology seems to correlate with the degree of Technetium Tc 99m Sestamibi uptake. A study in a dog myocardial infarction model reported that Technetium Tc 99m Sestamibi undergoes rapid myocardial uptake and washout. In general a single dose of Technetium Tc 99m Sestamibi administered for imaging studies is rapidly cleared from the blood, with an effective half-life of clearance (which includes both the biological half-life and the physical half-life) of approximately 60 minutes.

The following adverse reactions have been reported in a small number of patients and were compared with those occurring subsequent to the administration of the drug. As such, the reactions are not necessarily drug-related. The reactions consisted of the following symptoms: fever; hypotension; sensory; hypothermia characterized by dyspnea, hypotension, and injection site reactions; and one death. The deaths followed a second injection of Technetium Tc 99m Sestamibi imaging and who had coronary angiography within two hours after a second injection of Technetium Tc 99m Sestamibi. The mechanism of Technetium Tc 99m Sestamibi localization in various types of breast tissue (e.g., benign, inflammatory, metastatic) is not well understood. In general the histology seems to correlate with the degree of Technetium Tc 99m Sestamibi uptake.

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