Kit for the Preparation of Technetium Tc99m Pyrophosphate Injection
For Diagnostic Use, Rx Only

* Blood Pool Imaging: Diagnostic agent for the detection of gastrointestinal bleeding and for gated blood pool studies
* Cardiac imaging: Adjunctive diagnostic agent for detection of acute myocardial infarction
* Bone imaging: For demonstration of sites of altered osteogenesis

* Each 10 ml multidose reaction vial contains:
  * 12.0 mg sodium pyrophosphate
  * 2.8 mg minimum stannous tin and 4.9 mg maximum total tin as stannous chloride dihydrate
  * pH adjusted to 5.3 to 5.7
  * Contents lyophilized and sealed under nitrogen

* High tin content for increased red cell binding capacity

* Shelf life up to 12 months at room temperature storage

* Choice of 5-vial kit or 30-vial Convenience Pack
DESCRIPTION

Kit for the Preparation of Technetium Tc 99m Pyrophosphate Injection is a multidose reagent kit which contains the sterile, non-pyrogenic, non-radioactive ingredients necessary in preparing Technetium Tc 99m Pyrophosphate Injection for diagnostic use by intravenous administration. Each 30 ml vial contains 1.13 mg of sodium pyrophosphate in water. This amount is equivalent to a minimum stannous tin as stannous chloride dihydrate and 4.9 mg of sodium pyrophosphate. The lyophilized contents of the Kit for the Preparation of Technetium Tc 99m Pyrophosphate Injection are shown in table 3. Preparation of Technetium Tc 99m Pyrophosphate Injection must be done 1 to 6 hours following administration.

Physical Characteristics

Technetium Tc 99m decays by internal transition with a physical half-life of 6.02 hours. The radiochemical half-life is 60 minutes. (See table 5 for values of the relative attenuation of the radiation emitted by this radionuclide that results from interaction of different thicknesses of Pb is shown in Table 3. For example, the use of a 0.25 thickness of Pb will attenuate the radiation by a factor of 100, a thickness of 1.00 Pb will attenuate the radiation by a factor of 10,000.)

Shield Thickness

Coefficient of Attenuation

<table>
<thead>
<tr>
<th>Shield Thickness</th>
<th>Coefficient of Attenuation</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.017</td>
<td>0.95</td>
</tr>
<tr>
<td>0.08</td>
<td>0.5</td>
</tr>
<tr>
<td>0.08</td>
<td>0.5</td>
</tr>
<tr>
<td>0.16</td>
<td>10</td>
</tr>
<tr>
<td>0.25</td>
<td>10</td>
</tr>
<tr>
<td>0.33</td>
<td>0.3</td>
</tr>
</tbody>
</table>

To correct for physical decay of this radionuclide, the fraction that is not selected intervals after the time of calibration is shown in Table 3.

TABLE 3

Physical Decay Chart: Tc 99m, half-life 6.02 hours

Fraction Remaining at 6.02 Hours

<table>
<thead>
<tr>
<th>Time (hr)</th>
<th>Fraction Remaining</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1.00</td>
</tr>
<tr>
<td>0.5</td>
<td>0.994</td>
</tr>
<tr>
<td>1</td>
<td>0.988</td>
</tr>
<tr>
<td>1.5</td>
<td>0.984</td>
</tr>
<tr>
<td>2</td>
<td>0.980</td>
</tr>
<tr>
<td>3</td>
<td>0.976</td>
</tr>
<tr>
<td>4</td>
<td>0.972</td>
</tr>
<tr>
<td>5</td>
<td>0.968</td>
</tr>
<tr>
<td>6</td>
<td>0.964</td>
</tr>
</tbody>
</table>

If no calibrator is available, the calculated activity can be used to estimate the actual activity.

TABLE 4

Estimated Absorbed Radiation Doses

Bone and Cardiac Imaging*  
Technetium Tc 99m Pyrophosphate Injection

<table>
<thead>
<tr>
<th>Target Organ</th>
<th>mGy/555 MBq</th>
<th>rad/25 mCi</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Body</td>
<td>1.6</td>
<td>0.18</td>
</tr>
<tr>
<td>Head</td>
<td>0.6</td>
<td>0.07</td>
</tr>
<tr>
<td>Thorax</td>
<td>0.3</td>
<td>0.03</td>
</tr>
<tr>
<td>Head</td>
<td>0.3</td>
<td>0.03</td>
</tr>
<tr>
<td>Thorax</td>
<td>0.3</td>
<td>0.03</td>
</tr>
</tbody>
</table>

**Note:** The dose estimates are based on the in vivo dose distribution in animal studies and are intended for use as a guide to radiation safety. They are not necessarily accurate for the human condition and should not be used as a basis for radiation safety decisions.

CLINICAL PHARMACOLOGY

When administered intravenously, Technetium Tc 99m Pyrophosphate Injection has a specific affinity for areas of osseous activity. It is also considered a low mass, non-radioactive agent, possibly avoiding interference between low mass, non-radioactive agents.

When administered intravenously, Technetium Tc 99m Pyrophosphate Injection is collected in the blood pool. As a result, Technetium Tc 99m Pyrophosphate Injection is formed for intravenous administration.

Several factors, including the physical characteristics of the radionuclide, the dose of Technetium Tc 99m Pyrophosphate Injection, and the effectiveness of the calibration system immediately prior to administration.

CRITICAL SAFETY CONSIDERATIONS

The calibration system immediately prior to administration should be accurately adjusted prior to use.

ADVERSE REACTIONS

None known.

INDICATIONS AND USAGE

Calibration time

As indicated in the diagnosis of confirmed myocardial infarction (ECG and serum enzyme abnormalities), the incidence of false negative images is less than 10%. Positive images are obtained in approximately 10% of patients who have had a myocardial infarction. The incidence of false positive images has been found to be 9 to 10% percent. Such patients have concomitant disease or other therapeutic drug usage.

CONTRAINDICATIONS

None known.

WARNING

External Radiation

Technetium Tc 99m Pyrophosphate Injection is formed for diagnostic use by intravenous injection. When administered 30 minutes prior to the intravenous administration of Sodium Pertechnetate Tc 99m, it has an affinity for and is sequestered in the bone pool. In the average ADULT patient (70 kg) is: 0.16            10
0.08            10

The suggested dose range of the non-radioactive reconstituted Kit for the Preparation of Technetium Tc 99m Pyrophosphate Injection in the following procedure:

Bone and Cardiac Imaging*  
Technetium Tc 99m Pyrophosphate Injection

<table>
<thead>
<tr>
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<th>mGy/555 MBq</th>
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<tbody>
<tr>
<td>Total Body</td>
<td>1.6</td>
<td>0.18</td>
</tr>
<tr>
<td>Head</td>
<td>0.6</td>
<td>0.07</td>
</tr>
<tr>
<td>Thorax</td>
<td>0.3</td>
<td>0.03</td>
</tr>
</tbody>
</table>

DOSAGE AND ADMINISTRATION

Prior to use, reconstituted radionuclide Sodium Tc 99m Pertechnetate is used.

Bone Imaging: 185-555 megabecquerels (5-15 mCi)
Cardiac Imaging: 370-555 megabecquerels (10-15 mCi)

ADVERSE REACTIONS

The non-radioactive reconstituted agent should be injected by direct intravenous injection, if not contraindicated for the patient's cardiac condition, prior to the administration of Sodium Pertechnetate Tc 99m Injection as well as other radioactive preparations.

The solution should not be used if cloudy, discolored, or found to contain particulate matter.

The non-radioactive reconstituted agent should be used only by physicians who are qualified by training and experience in the safe use and handling of radioactive substances and whose expertise and training have been approved by the appropriate government agency authorized to license and regulate the use of radioactive substances.

No special handling is required for the non-radioactive drug product.

Bone Imaging

Bone and cardiac imaging should be performed immediately prior to administration when necessary. Other radiographic and nuclear imaging techniques should be avoided in the immediate post-injection period.

Cardiac Imaging

Patients with certain conditions should be started before obtaining the cardiac imaging procedure.

Effective Dose Equivalent

Effective dose equivalent is a quantity which may be used for purposes of radiation protection to estimate the effective dose received by an individual from multiple sources of radiation. It is recommended that the image be compared with the average ADULT patient (70 kg) is: 0.16            10
0.08            10

Assume 75% of the Sodium Pertechnetate Tc 99m labels red blood cells and the other 25% remains as Technetium Tc 99m Pyrophosphate Injection.

8. Withdrawals for administration must be made aesthetically using a sterile syringe and needle. The vias should not be vented. The withdrawal of doses for patient administration.

9. Assay withdrawal material with a sterile lead shielded syringe for 6 hours following preparation. For optimal results, this time should be minimized.

10. Record date and time of preparation.

11. Examine via card control for particulates and discoloration prior to injection.

12. Withdrawals for administration must be made aesthetically using a sterile syringe and needle. The vias should not be vented. The withdrawal of doses for patient administration.

13. Assay withdrawal material with a sterile lead shielded syringe for 6 hours following preparation. For optimal results, this time should be minimized.

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15. Examine via card control for particulates and discoloration prior to injection.

16. Withdrawals for administration must be made aesthetically using a sterile syringe and needle. The vias should not be vented. The withdrawal of doses for patient administration.

17. Assay withdrawal material with a sterile lead shielded syringe for 6 hours following preparation. For optimal results, this time should be minimized.

18. Record date and time of preparation.