To obtain rest and stress images, wait 10 minutes after completion of the rest dose infusion. Start imaging acquisition 60-90 seconds after completion of the infusion; if necessary, repeat the injection and administration procedure.

The recommended weight-based dose of rubidium Rb 82 is between 0.66 and 1.32 MBq (18–35 mCi) per kg of body weight, up to a maximum dose of 37 MBq (1 mCi) in any 24-hour period. This dose should be given intravenously. Rubidium Rb 82 chloride injection is indicated for intravenous use. Rubidium Rb 82 chloride injection is a radioactive diagnostic agent intended for administration into the circulation for the evaluation of myocardial perfusion. It is used as a radiopharmaceutical for diagnostic imaging procedures to determine the functional state of the myocardium under rest or pharmacologic stress conditions to evaluate regional myocardial perfusion, which in turn reflects contractile function. The recommended dose is typically 3-7 minutes long.

DOSAGE FORMS AND STRENGTHS

Rubidium Rb 82 chloride injection is a radiolabeled chloride ion solution. The chloride ion is the naturally occurring stable isotope Rb 82, which decays by beta radiation to Sr 82, a naturally occurring radioactive isotope. The chemical characteristics of rubidium chloride are the same as those of stable rubidium chloride.

DOSAGE FORMS AND STRENGTHS

Rubidium Rb 82 chloride injection is a clear colorless to light yellow solution intended for intravenous use as a radiopharmaceutical. It contains the radioisotope rubidium Rb 82 in the chloride ion. The concentration of rubidium Rb 82 chloride injection is approximately 0.8 μCi/μL (0.03 μCi/mL). It contains no additives and is supplied as an isotonic saline solution (0.9% NaCl). The total volume of solution is 1 mL.

DOSAGE FORMS AND STRENGTHS

Rubidium Rb 82 chloride injection is a radiopharmaceutical that is administered intravenously. The recommended dose is typically 3-7 minutes long.

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a function of generator age.

...estimate of the maximum available activity of Rubidium Rb 82 (Delivery Limit) as Certain doses, including the maximum recommended dose [60 mCi (2220 MBq)], An eluate Sr 85 level of 0.1 μCi/mCi (kBq/MBq) Rb 82.

2.7 RUBY-FILL Expiration

The system uses Table 2 to calculate the ratio (R) of Sr 85/Sr 82.

<table>
<thead>
<tr>
<th>Days</th>
<th>Ratio Factor</th>
<th>Days</th>
<th>Ratio Factor</th>
<th>Days</th>
<th>Ratio Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1.214</td>
<td>2</td>
<td>1.190</td>
<td>3</td>
<td>1.178</td>
</tr>
<tr>
<td>2</td>
<td>1.202</td>
<td>3</td>
<td>1.169</td>
<td>4</td>
<td>1.159</td>
</tr>
<tr>
<td>3</td>
<td>1.191</td>
<td>4</td>
<td>1.158</td>
<td>5</td>
<td>1.148</td>
</tr>
</tbody>
</table>

Table 2: Calculation of the Ratio of Sr 85 to Sr 82

2.8.7 Rb 82 Dose Delivery Limit Based on Generator Age

<table>
<thead>
<tr>
<th>Dose</th>
<th>Days</th>
<th>Ratio Factor</th>
<th>Effective Dose Per Unit Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 mCi</td>
<td>10</td>
<td>1.19</td>
<td>0.0005</td>
</tr>
<tr>
<td>20 mCi</td>
<td>10</td>
<td>1.19</td>
<td>0.05</td>
</tr>
<tr>
<td>50 mCi</td>
<td>10</td>
<td>1.19</td>
<td>0.15</td>
</tr>
</tbody>
</table>

Table 3: Rubidium Rb 82 Dose Delivery Limit Based on Generator Age1

1 Rb 82 doses are averages of rest and stress dosimetry data. To calculate organ doses (μGy) from the delivery limit, use the factor (R) listed for the organ on Table 3. The dose delivered to an organ is determined by multiplying a dose (μGy/kBq) by the fraction (R) of the Sr 85/Sr 82 ratio for the generator.

5.1 High Level Radiation Exposure with Use of Incorrect Eluent

Excess radiation exposure occurs when the Sr 82 and Sr 85 levels in rubidium Rb 82 exceed the generator's expiration limits. Use of incorrect eluent can cause high levels of Sr 82 and Sr 85 radioactivity levels in the eluate. Depending on the type of eluent used, Sr 85 activity levels can reach high levels of up to 50 mCi (1850 MBq) ppm. When solutions containing calcium ions are used to elute

6.2 Adverse Reactions

...adverse reactions in patients have been observed when solutions containing calcium ions are used to elute

8.4 Pediatric Use

...safety and effectiveness of rubidium Rb 82 chloride injection in pediatric patients has not been established. Use of this product in this age group is not recommended.

11.2 Physical Characteristics

...provides ± 10% accuracy for rubidium Rb 82 chloride doses between 370-2220 MBq (10-60 mCi).

12.1 Mechanism of Action

...blood flow brings Rb 82 to all areas of the body during the first pass of circulation. Blood flow is followed by accumulation in the myocardial capillaries and arterioles. The concentration of Rb 82 in the myocardium is increased by the cell membrane sodium-potassium (Na+/K+) ion exchange pumps that are present in cell membranes.

12.2 Pharmacodynamics

... providing ± 10% accuracy for rubidium Rb 82 chloride doses between 370-2220 MBq (10-60 mCi).