MDP
Kit for the Preparation of Technetium Tc99m Medronate for Injection
Diagnostic for Intravenous Use, Rx Only

- Indicated as a bone imaging agent to delineate areas of altered osteogenesis
- 20 mg medronic acid per vial
- Contains 1 mg of ascorbic acid for reconstituted stability
- Room temperature storage both before and after reconstitution
- Choice of 5-vial kit or 30-vial Convenience Pack

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Kit for the Preparation of Technetium Tc 99m Medronate for Injection

**DIAGNOSIS FOR INTRAVENOUS USE**
Rx Only

**DESCRIPTION:**
Kit for the Preparation of Technetium Tc 99m Medronate is a multidose reaction vial which contains the sterile, non-pyrogenic, non-ionic radiogold necessary to produce Technetium Tc 99m Medronate Injection for diagnostic use by Intravenous injection.

Each 10ml multidose vial contains:
- Medronic acid: 20 mg
- Assoronic acid: 1 mg
- Stannous fluoride: SnF₂: 0.13 mg (minimum)
  Total t/m (maximum, as stannous fluoride, SnF₂): 0.38 mg

The pH is adjusted to 6.5 (6.3 to 6.7) with sodium hydroxide and/or hydrochloric acid prior to lyophilization. No bacteriologic preservative is present in the vial. The contents of the vials are lyophilized and sealed under nitrogen at the time of manufacture. The structural formula is:

\[
\text{O} \quad \text{O} \\
\text{NaO} - \text{P} - \text{CH₂} - \text{P} - \text{ONa} \\
\text{OH} \quad \text{OH}
\]

When a solution of sterile, non-pyrogenic, oxidant-free Sodium Perchlorate Tc 99m Injection is added to the vial, the dose of Pd in technetium Tc 99m Medronate is formed for administration by intravenous injection. The pH of the reconstituted product is 5.4 to 6.0. The precise structure of Technetium Tc 99m Medronate Injection is not known at this time.

**PHYSICAL CHARACTERISTICS:**
Technetium Tc 99m decay by isomeric transition with a physical half-life of 6.02 hours. The principal photon that is useful for detection and imaging studies is listed in Table 1.

**TABLE 1**
Principal Radiation Emission Data

<table>
<thead>
<tr>
<th>Radiation</th>
<th>Mean % per Disintegration</th>
<th>Mean Energy (keV)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gamma-2</td>
<td>89.07</td>
<td>140.5</td>
</tr>
</tbody>
</table>

*Note: OC: Radioactive Decay Table, D00/79/10200, 10/20, 1979.*

**EXTERNAL RADIATION:** The specific gamma ray constant for Tc 99m is 0.78 R/mm²/hr at 1 cm. The first half-value layer is 0.017 of lead (Pb). A range of values for the relative attenuation of the radiation emitted by this radionuclide that results from interaction of the various thicknesses of Pb in Table 2. To facilitate control of the radiation exposure from milliunits of this radionuclide, the use of a 0.25 mm Pb filter will attenuate the radiation emitted by a factor of about 1,000.

**TABLE 2**
Attenuation by Lead Shielding

<table>
<thead>
<tr>
<th>Shield Thickness (cm)</th>
<th>Coefficient of Attenuation</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.017</td>
<td>0.5</td>
</tr>
<tr>
<td>0.08</td>
<td>10</td>
</tr>
<tr>
<td>0.16</td>
<td>100</td>
</tr>
<tr>
<td>0.25</td>
<td>1000</td>
</tr>
<tr>
<td>0.33</td>
<td>10000</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.*

**CLINICAL PHARMACOLOGY:**
During the initial 24 hours following intravenous injection of Technetium Tc 99m Medronate, about 50% of each dose is retained in the skeleton, and about 50% is excreted in the urine. Upon intravenous injection, Technetium Tc 99m Medronate exhibits a specific affinity for areas of altered osteogenesis. In humans, blood levels fall to 4 to 10% of the injected dose by two hours post-injection and to 3 to 5% by three hours.

Uptake of Technetium Tc 99m Medronate In bone appears to be related to osteogenic activity and to skeletal blood perfusion. The deposition in the skeleton is basically symmetrical, with increased uptake in the extremities. The Technetium Tc 99m Medronate appendicular skeleton, there is increased activity in the detail aspect on long bones as compared to the diaphyses.

**INDICATIONS AND USAGE:**
Technetium Tc 99m Medronate Injection may be used as a bone imaging agent to outline areas of altered osteogenesis.

**CONTRAINDICATIONS:**
None known.

**WARNINGS:**
This class of compounds is known to complex cations such as calcium. Particular caution should be used with patients who have, or may be predisposed to hypercalcemia (i.e., alkalosis).

**PRECAUTIONS:**
- Precautions reports indicate impairment of brain scans using Sodium Perchlorate Tc 99m Injection which have been preceded by a bone scan using an agent which contains sodium perchlorate. The reasons may not be purely false-positive or false-negative brain scans.
- It is recommended, wherever feasible, to precede bone imaging procedures. Alternatively, a brain imaging agent such as Technetium Tc 99m Medronate should be employed.

**ADVERSE REACTIONS:**
Serious adverse reaction due to Technetium Tc 99m Medronate Injection have been reported. These usually hypersensitivity reactions characterized by various skin rashes, hypotension, chills, nausea and vomiting. There have also been rare cases of anaphylaxis and anaphylactic shock with the use of Technetium Tc 99m Medronate.

**DOSAGE AND ADMINISTRATION:**
Shielding should be utilized when preparing Technetium Tc 99m Medronate Injection.

**PREPARATION:**
A preparation with oxidant-free Sodium Perchlorate Tc 99m Injection, the suggested dose range of Technetium Tc 99m Medronate Injection in the average ADULT patient (70 kg) is:

- 370-740 megabequerels (10-20 millibecquerels) given intravenously.
- Imaging is optimal 1 to 4 hours post injection.

**Radiopharmacy:**
Drug products should be inspected visually for particulate matter and disconnection prior to administration whenever solution and container appear intact.

**Patient dose should be measured by a suitable radiocactivity calibration system immediately prior to administration.**

**Radiation Dosimetry:**
The effective half-life was assumed to be the physical half-life for all calculated values. The estimated radiated absorbed doses to an average ADULT patient (70 kg) from an intravenous injection of a maximum of 740 megabequerels (20 millibecquerels) of Technetium Tc 99m Medronate Injection are shown in Table 4.

**HOW SUPPLIED:**
Kit for the Preparation of Technetium Tc 99m Medronate Injection is supplied in kits. Each kit contains:
- Thirty (30) sterile, non-pyrogenic vials. Each 10 ml multidose contains 20 mg medicated acid, 1 mg medicated acid, 0.3 mg of stannous fluoride, 0.38 mg of magnesium tin, as stannous fluoride, SnF₂, in lyophilized form. The pH is adjusted with sodium hydroxide and/or hydrochloric acid prior to lyophilization. The vial does not contain any preservative.
- Ten (10) 5 ml lyophilized and sealed under nitrogen at the time of manufacture. The pH of the reconstituted product is 5.4 to 6.0.

**Included in each (5) vial kit is one (1) package insert and ten (10) label packages. Included in each (1) 30 vial kit is one (1) package insert and sixty (60) label packages.

**Storage:**
Store the product as supplied at 20-25°C (68-77°F). After reconstitution, store at 0-25°C (32-77°F). [See USP (see DOSAGE AND ADMINISTRATION).]

**DIRECTIONS FOR PREPARATION OF TECHNETIUM Tc 99m MEDRONATE INJECTION:**

The lyophilized powder in the reaction vial is sterile and non-pyrogenic and does not contain a preservative. Shielded syringes and aseptic procedures normally employed in radiopharmacy may be used to withdraw from sterile, non-pyrogenic containers should be used during addition of perchlorate solution to the reaction vial and the withdrawal of doses for patient administration.

**For Technetium Tc 99m must be diluted prior to injection into the reaction vial only Sodium Chloride Injection USP 0.9% (without preservative) should be used.

**Technetium Tc 99m Medronate Injection is prepared from Kit for the Preparation of Technetium Tc 99m Medronate for Injection by the following aseptic procedure:**
1. Remove the plastic disk from the vial and the label from the top of the vial closures with alcohol to sanitize the surface.
2. Complete the radiation label and affix to the vial. Place the reaction vial in a suitable radiation shield.
3. With a sterile, shielded syringe aseptically obtain 0.5-1.0 mL of the lyophilized, sterile, non-pyrogenic Sodium Perchlorate Tc 99m Injection containing more than 15.0 mg of magnesium tin (300 milligrams). Aseptically add the Sodium Perchlorate Tc 99m Injection the vial be swabbed with a nitrogen atmosphere in the vial by not introducing air during reconstitution.
4. Swill the contents of the vial for one minute, and return the vial to the lead shield.
5. Record time and date of preparation.
6. The radiochemical purity of the prepared radiopharmaceutical should be checked prior to patient administration.
7. Examine vial contents for particulates and discoloration prior to injection. Do not use if not clear.
8. Withdrawal for administration must be made aseptically using a sterile syringe and needle.
9. Since the vials are lyophilized to prevent oxidation of the complex, the vials should not be vortexed. If repeated withdrawals are made from the vial, the replacement of contents with air should be minimized.
10. Use within six (6) hours of preparation. For optimum results, this time should be minimized. The vial contains no bacteriostatic preservative. After reconstitution store at 20-25°C (68-77°F) [See USP (see DOSAGE AND ADMINISTRATION).]

**NDQB 45567 0400 (1 vial pack)**

**NDQB 45567 0402 (30 vial pack)**

*This reagent kit for the preparation of a radiopharmaceutical is approved for use by persons licensed pursuant to Section 120.547, Code of Massachusetts Regulation 105, or under equivalent licensing of the U.S. Nuclear Regulatory Commission or an Agreement State.*

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