**MDP Skeletal Agent**

**Description**
Each vial contains 10 mg medronic acid, 0.84 mg Tin(II) Chloride and 2.0 mg of ascorbic acid. Hydrochloric acid is used in the manufacture. Before lyophilisation the pH is adjusted to 5.0 with sodium hydroxide solution. The contents of the vial are lyophilized and stored under nitrogen.

As supplied the product is sterile and pyrogen free. It contains no preservative.

The product is designed for diagnostic use. Use by intravenous administration after reconstitution with sodium pertechnetate (99mTc) injection.

**Physical Characteristics of 99mTc**
Technetium-99m with a physical half life of six hours, decays by isomeric transition to 99Tc. Photons associated with this transition that are useful for detection and imaging studies are listed in Table 1.

**Table 1**
**Principal Radiation Emission Data**

<table>
<thead>
<tr>
<th>Principal Radiation</th>
<th>Mean % per Disintegration</th>
<th>Mean Energy (kEV)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gamma-2</td>
<td>89.1</td>
<td>140.5</td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th>Hours</th>
<th>Fraction Remaining</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1.000</td>
</tr>
<tr>
<td>1</td>
<td>0.891</td>
</tr>
<tr>
<td>2</td>
<td>0.794</td>
</tr>
<tr>
<td>3</td>
<td>0.707</td>
</tr>
<tr>
<td>4</td>
<td>0.630</td>
</tr>
<tr>
<td>5</td>
<td>0.561</td>
</tr>
<tr>
<td>6</td>
<td>0.500</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hours</th>
<th>Fraction Remaining</th>
</tr>
</thead>
<tbody>
<tr>
<td>7</td>
<td>0.445</td>
</tr>
<tr>
<td>8</td>
<td>0.397</td>
</tr>
<tr>
<td>9</td>
<td>0.354</td>
</tr>
<tr>
<td>10</td>
<td>0.315</td>
</tr>
<tr>
<td>11</td>
<td>0.281</td>
</tr>
<tr>
<td>12</td>
<td>0.250</td>
</tr>
</tbody>
</table>

**External Radiation**
The specific gamma ray constant for 99mTc is 0.19mGy per MBq h at 1 cm. The first half value thickness of lead (Pb) for 99mTc is 0.2mm. Attenuation by lead is given in the following table:

**Table 2:**
**Physical Decay Chart of 99mTc**

<table>
<thead>
<tr>
<th>Shield Thickness mm Pb</th>
<th>Coefficient of Attenuation</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.95</td>
<td>0.1</td>
</tr>
<tr>
<td>1.8</td>
<td>0.01</td>
</tr>
<tr>
<td>2.7</td>
<td>0.001</td>
</tr>
<tr>
<td>3.6</td>
<td>0.0001</td>
</tr>
</tbody>
</table>
Pharmacology

Upon intravenous injection, skeletal uptake of technetium (99mTc) MDP appears to be related to bone metabolic activity and to skeletal blood flow. Technetium (99mTc) MDP exhibits a specific affinity for areas of altered osteogenesis.

Localized areas of decreased skeletal accumulation of technetium (99mTc) MDP may be seen after therapeutic external irradiation. Technetium (99mTc) MDP has been known to accumulate in areas of acute myocardial infarction from one to fourteen days after the initial event.

During the first 24 hours post injection about 50% of the dose is renally excreted; less than 2% of the dose remains in the vascular system. Blood levels fall to 3-5% of the injected dose by three hours post injection.

Indications

Technetium (99mTc) MDP may be used as a bone imaging agent to delineate areas of altered osteogenesis.

Contraindications

None known.

Precautions

General

Radiopharmaceuticals should be used only by physicians who are qualified and licensed to handle radioactives. Contents of the vial are intended only for use in the preparation of technetium (99mTc) MDP. They should not be administered directly to the patient. Technetium (99mTc) MDP should be formulated within six hours prior to use. Imaging should be carried out between one and four hours after injection.

Dose Handling

Radiation exposure to clinical personnel must be minimized. Care and appropriate safety measures should always be used. The radioactivity of the dose should be checked with a suitable instrument immediately prior to administration. Disposal of all radioactive wastes should be carried out in accordance with the NH & MRC “Code of Practice for the Disposal of Radioactive Wastes by the User” 1985.

Patient Care

Care should be taken to minimize unwanted radiation exposure to patients, consistent with proper patient management.

In order to reduce radiation dose to the bladder the patient should be encouraged to drink fluids and to void as frequently as possible following the administration of the radiopharmaceutical for a period of four to six hours.

Use during Pregnancy

It is not known if technetium (99mTc) MDP can cause foetal harm when administered to a pregnant woman. Technetium (99mTc) should only be given to a pregnant woman if in the judgement of the treating physician the expected benefits outweigh the potential hazards.

Use during Lactation

Technetium (99mTc) is excreted in human milk. If administered to a nursing mother, formula feeding must be substituted.

Adverse Reactions

Adverse reactions have not been reported that are specifically attributable to the use of technetium (99mTc) MDP. Allergic dermatological manifestations (erythema) have been infrequently reported with other similar agents.

Note Adequate long-term studies have not been performed in animals to determine whether this drug affects fertility, or has teratogenic or mutagenic potential. Safety and efficacy in children have not been established.
Dosage and Administration

Technetium (99mTc) MDP Skeletal Agent is prepared for clinical use as follows:

1. Using an aseptic technique add the required amount of sodium pertechnetate (99mTc) solution to a vial of the reagent. The volume of solution added should be in the range 3-8mL and the maximum activity should be 15GBq.

2. Mix by shaking gently for approximately 10 seconds.

3. Administer by IV injection.

Note

1. The vial is sealed under nitrogen. A vent needle should be used when adding the pertechnetate solution to the vial.

2. After reconstitution with sodium pertechnetate (99mTc) the contents are radioactive and adequate shielding and handling precautions must be maintained.

3. Using proper shielding, the vial containing the reconstituted solution should be visually inspected to ensure it is free from particulate matter.

4. The product should be used as soon as possible after reconstitution.

The suggested dose range for IV administration to be used in the average patient (70kg) is:

Bone Imaging: 370-740 MBq of technetium (99mTc) MDP.

The patient dose should be measured by a suitable radioactivity calibrator immediately before the administration. Radiochemical purity should be checked prior to patient administration. Shielding should be used when preparing technetium (99mTc) MDP.

Scanning post injection is optimal at about one to four hours.

Radiation Dosimetry

The estimated absorbed radiation doses to a standard (70kg) patient from a maximum dose of 740MBq of technetium (99mTc) MDP are shown in Table 4. As approximately half of the injected activity is excreted in the urine, the dose to the bladder and other organs will depend upon the patients voiding pattern.

Table 4:

The absorbed radiation doses following injection of the maximum recommended dose of (99mTc) MDP bone agent (740 MBq) are estimated to be:

<table>
<thead>
<tr>
<th>Effect</th>
<th>Dose (mGy)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bone surface</td>
<td>46 mGy</td>
</tr>
<tr>
<td>Red marrow</td>
<td>7.1 mGy</td>
</tr>
<tr>
<td>Kidneys</td>
<td>5.4 mGy</td>
</tr>
<tr>
<td>Bladder wall</td>
<td>37 mGy</td>
</tr>
<tr>
<td>GT-LT.</td>
<td>2.8 mGy</td>
</tr>
<tr>
<td>Ovaries</td>
<td>2.6 mGy</td>
</tr>
<tr>
<td>Testes</td>
<td>1.8 mGy</td>
</tr>
</tbody>
</table>

Effective Dose Equivalent: 5.9 mSv


Note:
In order to reduce radiation dose to the bladder the patient should be encouraged to drink fluids and to void as frequently as possible following the administration of the radiopharmaceutical for a period of four to six hours.
**MDP Skeletal Agent**

**Presentation**
MDP Skeletal Agent kit is a set of five sterile and pyrogen free multi-dose vials. Each vial is packed under nitrogen and contains:

- Medronic Acid: 10.0 mg
- Tin (II) Chloride: 0.84 mg
- Ascorbic Acid: 2.0 mg

**Expiry**
Expiry is 24 months after manufacture. The expiry date is found on the vial label and on the pack. Studies have shown that the product is stable at 30°C and 40°C for a limited time.

**Storage**
Store between 2-8°C.
(Refrigerate. Do not freeze).

TGA Approval Date: 18th January 1991.

Product No: 10168

AUST R: 10333

**Contact Details**

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ANSTO Health is a commercial enterprise of the Australian Nuclear Science and Technology Organisation (ANSTO), which is located at Lucas Heights, in Sydney, N.S.W.

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