PRODUCT INFORMATION

MDP

Kit for preparation of Technetium (^{99m}Tc) medronate power for injection vial

Description

Each vial contains 5.00 mg Methylene Diphosphonic Acid i.e. Medronic Acid (Equivalent to 6.25 mg of Sodium salt of Methylene Diphosphonic Acid), 0.417 mg Stannous Chloride Dihydrate and 2.0 mg of Ascorbic Acid. Hydrochloric Acid and Sodium Hydroxide are used in the manufacture. Before lyophilisation the pH is adjusted to 6.0 with Sodium Hydroxide or Hydrochloric Acid solutions. 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 (^{99m}Tc) injection solution.

Physical Characteristicsof ^{99m}Tc

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

Table 1
Principal Radiation Emission Data

Principal Radiation	Mean % per Disintegration	Mean Energy (keV)
Gamma-2	89.1	140.5

Reference: "D A Weber, K F Eckerman, LT Dillman and JC Ryan. MIRD: Radionuclide and Decay Schemes." The society of Nuclear Medicine Inc. New York, 1989.

Table 2:
Physical Decay Chart of ^{99m}Tc

Hours	Fraction Remaining	Hours	Fraction Remaining
0	1.000	7	0.445
1	0.891	8	0.397
2	0.794	9	0.354
3	0.707	10	0.315
4	0.630	11	0.281
5	0.561	12	0.250
6	0.500		

External Radiation

The specific gamma ray constant for ^{99m}Tc is 0.19mGy per MBq^{-h} at 1 cm. The first half value thickness of lead (Pb) for ^{99m}Tc is 0.2mm. Attenuation by lead is given in the following table:

Table 3:
Radiation Attenuation by Lead Shielding

Shield Thickness mm Pb	Coefficient of Attenuation
0.95	0.1
1.8	0.01
2.7	0.001
3.6	0.0001

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Pharmacology

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

Localized areas of decreased skeletal accumulation of technetium (^{99m}Tc) MDP may be seen after therapeutic external irradiation. Technetium (^{99m}Tc) 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 (^{99m}Tc) 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 (^{99m}Tc) MDP. They should not be administered directly to the patient. Technetium (^{99m}Tc) 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 (^{99m}Tc) MDP can cause foetal harm when administered to a pregnant woman. Technetium (^{99m}Tc) 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 (^{99m}Tc) 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 (^{99m}Tc) 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 (^{99m}Tc) MDP is prepared for clinical use as follows:

(1) Using an aseptic technique add the required amount of sodium pertechnetate (^{99m}Tc) 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 (^{99m}Tc) 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 (^{99m}Tc) 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 (^{99m}Tc) 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 (^{99m}Tc) MDP are shown in Table4. 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 (^{99m}Tc) MDP bone agent (740 MBq) are estimated to be:

Bone surface	46 mGY
Red marrow	7.1 mGY
Kidneys	5.4 mGY
Bladder wall	37 mGY
GT-LLT.	2.8 mGY
Ovaries	2.6 mGY
Testes	1.8 mGY

Effective Dose Equivalent: 5.9 mSv

Reference: ICRP Publication 53 (1987) Radiation dose to Patients from Radiopharmaceuticals.

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.

Presentation

MDP pack contains 6 single dose vials, each vial for use in one patient on one occasion only. Contains no antimicrobial preservative. Each vials is packed under nitrogen and contains:

Medronic Acid	5.0 mg
Stannous Chloride Dihydrate	0.417 mg
Ascorbic Acid	2.0 mg
Hydrochloric Acid	QS
Sodium Hydroxide	QS

Expiry

Expiry is 12 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).

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