TechneScan® MDP

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TechneScan® MDP
Kit for the Preparation of Technetium Tc 99m Medronate

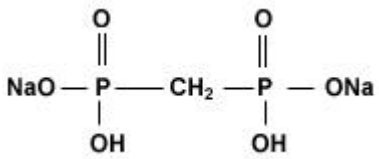
Diagnostic for Intravenous Use

DESCRIPTION

TechneScan® MDP Kit for the Preparation ot Technetium Tc 99m Medronate is a multidose reaction vial which contains the sterile, non-pyrogenic, non-radioactive ingredients necessary to produce Technetium Tc 99m Medronate Injection for diagnostic use by intravenous injection.

Each 10 mL multidose vial contains 10 mg medronic acid, 0.60 mg minimum stannous tin as stannous chloride dihydrate and 1.10 mg maximum total tin as stannous chloride dihydrate in lyophilized form. The pH is adjusted to 5.0-5.5 with sodium hydroxide and/or hydrochloric acid prior to lyophilization. No bacteriostatic preservative is present. Sealed under nitrogen.

The chemical names are: (1) Phosphonic acid, methylenebis-, disodium dihydrogen salt; (2) Disodium dihydrogen methylenediphosphonate. The structural formula is:



When a solution of sterile, non-pyrogenic, oxidant-free, isotonic Sodium Pertechnetate Tc 99m Injection is added to the vial, Technetium Tc 99m Medronate Injection is formed. The product so derived is intended for intravenous injection. The precise structure ot Technetium Tc 99m Medronate Injection is not known at this time.

Physical Characteristics
Technetium Tc 99m decays by isomeric transition with a physical half-life of 6.02 hours.[1] The principal photon that is useful for detection and imaging studies is listed in Table 1.

Table 1. Principal Radiation Emission Data

Radiation	Mean Percent Per Disintegration	Mean energy (keV)
Gamma-2	89.07	140.5

The specitic gamma ray constant for Tc 99m is 0.78 R/millicurie-hr at 1 cm. The first half-value layer is 0.017 cm of lead (Pb). A range of values for the relative attenuation of the radiation emitted by this radionuclide that results from interposition of various thicknesses of Pb is shown in Table 2. For example, the use of a 0.25 cm thickness of Pb will attenuate the radiation emitted by a factor of about 1,000.

Table 2. Radiation Attenuation by Lead Shielding

Shield Thickness (Pb) cm	Coefficient of Attenuation
0.017	0.5
0.08	10^{-1}
0.16	10^{-2}
0.25	10^{-3}
0.33	10^{-4}

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.

Table 3. Physical Decay Chart: Tc 99m, half-life 6.02 hours

Hours	Fraction Remaining	Hours	Fraction Remaining
0*	1.000	7	0.447
1	0.891	8	0.398
2	0.794	9	0.355
3	0.708	10	0.316
4	0.631	11	0.282
5	0.562	12	0.251
6	0.501		

•Calibration time

CLINICAL PHARMACOLOGY

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

Uptake of Technetium Tc 99m Medronate Injection in bone appears to be related to osteogenic activity and to skeletal blood perfusion. The deposition in the skeleton is bilaterally symmetrical, with increased accumulation in the axial structure as compared to the appendicular skeleton. There is increased activity in the distal aspect of long bones as compared to the diaphyses.

INDICATIONS AND USAGE

Technetium Tc 99m Medronate Injection may be used as a bone imaging agent to delineate 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 hypocalcemia (i.e., alkalosis).

Preliminary reports indicate impairment of brain scans using Sodium Pertechnetate Tc 99m Injection which have been preceded by a bone scan using an agent containing stannous ions. The impairment may result in false-positive or false-negative brain scans. It is recommended, where feasible, that brain scans precede bone imaging procedures. Alternatively, a brain imaging agent such as Technetium Tc 99m Pentetate Injection may be employed.

PRECAUTIONS

General

Contents of the vial are intended only for use in the preparation of Technetium Tc 99m Medronate Injection and are NOT to be administered directly to the patient.

Technetium Tc 99m Medronate Injection as well as other radioactive drugs must be handled with care, and appropriate safety measures should be used to minimize radiation exposure to the patient and clinical personnel consistent with proper patient management.

To minimize radiation dose to the bladder, the patients should be encouraged to drink fluids and to void immediately before the examination and as often thereafter as possible for the next 4-6 hours.

Technetium Tc 99m Medronate Injection should be formulated within six (6) hours prior to clinical use. Optimal imaging results are obtained 1-4 hours after administration.

The finding of an abnormal concentration of radioactivity implies the existence of underlying pathology, but further study is required to distinguish benign from malignant lesions.

The image quality may be adversely affected by obesity, old age, or impaired renal function .

The components of the kit are sterile and non-pyrogenic. It is essential to follow directions carefully and to adhere to strict aseptic procedures during preparation.

Technetium Tc 99 labeling reactions involved depend on maintaining the stannous ion in the reduced state. Hence, Sodium Pertechnetate Tc 99m Injection containing oxidants should not be used.

The preparation contains no bacteriostatic preservative. Technetium Tc 99m Medronate Injection should be stored at 15-30°C and discarded 6 hours after reconstitution. The solution should not be used it the contents are cloudy.

Vials are sealed under nitrogen: air or oxygen is harmful to the contents of the vials and the vials should not be vented.

The components of TechneScan® MDP are supplied sterile and non-pyrogenic. Aseptic procedures normally employed in making additions and withdrawals for sterile, non-pyrogenic containers should be used during addition of the pertechnetate solution and the withdrawal of doses for patient administration.

Shielding should be utilized when preparing Technetium Tc 99m Medronate Injection.

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

Radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radionuclides, and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides.

Carcinogenesis, Mutagenesis, Impairment of Fertility

No long-term animal studies have been performed to evaluate carcinogenic potential or whether Technetium Tc 99m Medronate Injection affects fertility in males or females. Mutagenesis studies have not been conducted.

Pregnancy Category C

Animal reproduction and teratogenicity studies have not been conducted on Technetium Tc 99m Medronate Injection. It is also not known whether Technetium Tc 99m Medronate Injection can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Technetium Tc 99m Medronate lnjection should be given to a pregnant woman only if clearly needed.

Ideally examinations using radiopharmaceuticals, especially those elective in nature, on a woman of childbearing capability, should be performed during the first few (approximately 10) days following the onset of menses.

Nursing Mothers

Technetium Tc 99m Medronate Injection is excreted in human milk during lactation; therefore, formula feeding should be substituted for breast feeding.

Pediatric Use

Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

Several adverse reactions due to Technetium Tc 99m Medronate Injection have been reported. These were usually hypersensitivity reactions characterized by itching, various skin rashes, hypotension, chills, nausea and vomiting.

There have also been rare cases of dizziness and asthenia associated with the use of Technetium Tc 99m Medronate.

DOSAGE AND ADMINISTRATION

Shielding should be utilized when preparing Technetium Tc 99m Medronate Injection .

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

370 - 740 megabecquerels: (10-20 millicuries) given intravenously. Scanning is optimal at 1-4 hours post injection.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

The patient dose should be measured by a suitable radioactivity 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 radiation absorbed doses to an average ADULT patient (70kg from an intravenous injection of a maximum of 740 megabecquerels (20 millicuries) of Technetium Tc 99m Medronate Injection are shown in Table 4.

Table 4. Estimated Absorbed Radiation Dose[2]
Technetium Tc 99m Medronate

Organ		mGy/740 MBq	rads/20 mCi
Total Body		1.3	0.13
Bone Total		7.0	0.70
Red Marrow		5.6	0.56
Kidneys		8.0	0.80
Liver		0.6	0.06
Bladder Wall	2 hour void	26	2.60
	4.8 hour void	62	6.20
Ovaries	2 hour void	2.4	0.24
	4.8 hour void	3.4	0.34
Testes	2 hour void	1.6	0.16
	4.8 hour void	2.2	0.22

HOW SUPPLIED

The TechneScan® MDP Kit for the Preparation of Technetium Tc 99m Medronate is supplied either as a set of 5 or 30 sterile, non-pyrogenic and grey-capped vials. Each 10 mL multidose vial contains 10 mg medronic acid, 0.60 mg minimum stannous tin as stannous chloride dihydrate and 1.10 mg maximum total tin as stannous chloride dihydrate in lyophilized form. The pH is adjusted with sodium hydroxide and/or hydrochloric acid to 5.0-5.5 prior to lyophilization. No bacteriostatic preservative is present. Sealed under nitrogen. Included in each 5-vial kit are one package insert and 10 radiation labels. Included in each 30-vial kit are one package insert and 60 radiation labels. Store the kit as packaged at 15-30^0 C.

Directions for Use

Technetium Tc 99m Medronate Injection is prepared from TechneScan® MDP by the following aseptic procedure:

1. Waterproof gloves should be worn during the preparation procedure. Remove the grey flip-off cap from the TechneScan® MDP vial and swab the top of the vial closure with alcohol.

2. Complete the radiation label and affix to the vial. Place the vial in an appropriate lead-capped radiation shield labeled and identified.

3. With a sterile shielded syringe, aseptically obtain 1-8 mL of a suitable, oxidant free, sterile and non-pyrogenic Sodium Pertechnetate Tc 99m Injection containing no more than 11.1 gigabecquerels (300 millicuries). Aseptically add the Sodium Pertechnetate Tc 99m Injection to the vial.

4. Swirl the contents of the vial for one minute, and let stand for at least 10 minutes.

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 solution is cloudy.

8. Withdrawals for administration must be made aseptically using a sterile shielded syringe and needle. Since the vials contain nitrogen to prevent oxidation of the complex, the vials should not be vented. If repeated withdrawals aremade from a vial, the replacement of contents with air should be minimized.

9. Aseptically withdraw material with a sterile shielded syringe for use within six (6) hours of preparation. For optimal results, this time should be minimized. The vial contains no bacteriostatic preservative. Store the reconstituted vial at 15-30°C. Discard the vial six (6) hours after reconstitution.

10. The patient dose should be measured by a suitable radioactivity calibration system immediately prior to administration.

"This radiopharmaceutical is approved by the U.S. Nuclear Regulatory Commission for distri bution to persons licensed pursuant to Sections 35.14 and 35.100 of 10 CFR Part 35 (superseded), or Section 35.200 of 10 CFR Part 35, effective April 1, 1987, or under equivalent licenses issued by an Agreement State."

[1]K ocher DC: Radioactive decay data tables. DOE/TIC-11026: 108, 1981

[2]Method of calculation: "S", Absorbed Dose Per Unit Cumulated Activity for Selected Radionuclides and Organs, MIRD Pamphlet No 11 (1975)

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