Technescan™ HDP

(Kit for the Preparation of Technetium Tc 99m Oxidronate Injection)

For Intravenous Use

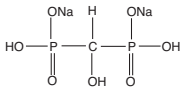
DESCRIPTION

Drug Characteristics

Technescan™ HDP (kit for the preparation of technetium Tc 99m oxidronate injection) is a radioactive diagnostic drug for intravenous use after radiolabeling with sodium pertechnetate Tc 99m injection.

Each vial contains 3.15 mg oxidronate sodium and 0.258 mg, minimum, stannous chloride ($SnCl_2 \cdot 2H_2O$), 0.297 mg, theoretical, stannous chloride ($SnCl_2 \cdot 2H_2O$) with 0.343 mg, maximum, tin chloride [stannous and stannic] dihydrate as $SnCl_2 \cdot 2H_2O$, and the following inactive ingredients: 0.84 mg gentisic acid as a stabilizer and 30 mg sodium chloride. The pH is adjusted with hydrochloric acid and/or sodium hydroxide. The pH of the radiolabeled drug is between 4.0 and 5.5. The vial contains a sterile, non-pyrogenic, lyophilized powder packaged under nitrogen.

The chemical structure of oxidronate sodium is:



The structure of the technetium Tc 99m oxidronate complex is unknown.

Nuclear Physical Characteristics

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

Table 1. Principal Radiation Emission Data

Radiation	Mean % per Disintegration	Energy (keV)
Gamma-2	89.07	140.5

The specific gamma ray constant for technetium-99m is 0.795 R/hr-mCi at 1 cm. The first half-value layer is 0.023 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 0.27 cm of Pb will attenuate the external radiation emitted by a factor of about 1,000.

Table 2. Radiation Attenuation by Lead Shielding

Shield Thickness (Pb) cm	Coefficient of Attenuation
0.023	0.5
0.09	10^{-1}
0.18	10^{-2}
0.27	10^{-3}

To correct for physical decay of this radionuclide, the fractions that remain at selected time intervals after the time of calibration are shown in Table 3.

Table 3. Physical Decay Chart: Technetium-99m, Half-Life 6.02 Hours

Hours	Fraction Remaining	Hours	Fraction Remaining
0*	1	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 24 hours following injection, technetium Tc 99m oxidronate is cleared from blood and other non-osseous tissues and accumulates in the skeleton and urine in humans. Blood levels are about 10% of the injected dose at one hour post-injection and continue to fall to about 6%, 4% and 3% at 2, 3, and 4 hours, respectively. When measured at 24 hours following its administration, skeletal retention is approximately 50% of the injected dose. Technetium Tc 99m oxidronate exhibits its greatest affinity for areas of altered osteogenesis and actively metabolizing bone.

INDICATIONS AND USAGE

Technescan HDP, after radiolabeling with sodium pertechnetate Tc 99m, is indicated for skeletal imaging to demonstrate areas of altered osteogenesis in adult and pediatric patients.

CONTRAINDICATIONS

None known.

WARNINGS

Technetium Tc 99m oxidronate may cause life-threatening hypersensitivity reactions. Have cardiopulmonary resuscitation equipment and personnel available and monitor all patients for hypersensitivity reactions. (See **ADVERSE REACTIONS**.)

Technetium Tc 99m oxidronate is known to complex cations such as calcium. Particular caution should be used with patients who have or who may be predisposed to hypocalcemia.

The biodistribution of technetium Tc 99m oxidronate may be altered in the presence of high levels of certain cations (iron, calcium, and aluminum). This may result in reduced uptake of radionuclide in the skeleton and increased extraosseal uptake, which may potentially degrade imaging quality. High levels of these cations may be caused by concomitant medications or medical conditions (e.g., iron overload, hypercalcemia, etc.). Most cases were observed after iron infusion. (See **PRECAUTIONS, Drug Interactions.**)

PRECAUTIONS

General

Technetium Tc 99m oxidronate contributes to a patient's overall long-term cumulative radiation exposure. Long-term cumulative radiation exposure is associated with an increased risk of cancer. Ensure safe drug handling to protect patients and healthcare providers from unintentional radiation exposure. (See **DOSAGE AND ADMINISTRATION, Radiation Safety-Drug Handling**.) To minimize radiation dose to the bladder, encourage patients to drink fluids before and after administration and to void immediately before the examination and as often thereafter as possible for the next 4 to 6 hours.

Drug Interactions

The biodistribution of technetium Tc 99m oxidronate may be altered in the presence of high levels of certain cations (iron, calcium, and aluminum). This may result in reduced uptake of radionuclide in the skeleton and increased extraosseal uptake, which may potentially degrade imaging quality. In patients with high levels of these cations caused by concomitant medications, particularly patients receiving iron infusions, consider performing an imaging study with technetium Tc 99m oxidronate injection once the cation levels have normalized (e.g., after 3 to 5 half-lives of the cation). (See **WARNINGS**.)

Carcinogenesis, Mutagenesis, Impairment of Fertility

No long-term animal studies have been performed to evaluate carcinogenic or mutagenic potential or whether technetium Tc 99m oxidronate affects fertility in males and females.

Pregnancy

Animal reproduction studies have not been conducted with technetium Tc 99m oxidronate. It is also not known whether technetium Tc 99m oxidronate can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity.

All radiopharmaceuticals, including Tehnescan HDP, have the potential to cause fetal harm depending on the fetal stage of development and the magnitude of the radiation dose. If considering Technescan HDP administration to a pregnant woman, inform the patient about the potential for adverse pregnancy outcomes based on the radiation dose from technetium Tc 99m oxidronate and the gestational timing of exposure.

Nursing Mothers

Technetium-99m is excreted in human milk during lactation, therefore formula feedings should be substituted for breast feedings.

Pediatric Use

Technescan HDP, after radiolabeling with sodium pertechnetate Tc 99m, is indicated for skeletal imaging to demonstrate areas of altered osteogenesis in pediatric patients.

The relatively higher effective dose and radiation exposure of the epiphyses in growing bone should be considered in pediatric patients. (See **DOSAGE AND ADMINISTRATION, Radiation Dosimetry**).

Geriatric Use

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

ADVERSE REACTIONS

The following adverse reactions associated with the use of Technescan HDP have been reported: hypersensitivity reactions, including life-threatening reactions, as well as nausea, vomiting, and injection site reactions.

OVERDOSAGE

In the event of the administration of an overdose of Technetium Tc 99m Oxidronate Injection, encourage patients to drink fluids and void frequently to reduce the radiation dose to the patient.

DOSAGE AND ADMINISTRATION

Radiation Safety – Drug Handling

After radiolabeling of Technescan HDP, the reaction vial contains Technetium Tc 99m Oxidronate Injection. Handle Technetium Tc 99m Oxidronate Injection with appropriate safety measures to minimize radiation exposure. (See **PRECAUTIONS, General**.) Use waterproof gloves, effective radiation shielding, and other appropriate safety measures when preparing and handling Technetium Tc 99m Oxidronate Injection.

Radiopharmaceuticals should be used by or under the control of healthcare providers who are qualified by specific training and experience in the safe use and handling of radionuclides, and whose experience and training have been approved by the appropriate governmental agency authorized to license the use of radionuclides.

Recommended Dosage

Adults

The recommended amount of radioactivity of Technetium Tc 99m Oxidronate Injection in adults is 555 MBq (15 mCi) with a range of 370 MBq to 740 MBq (10 mCi to 20 mCi).

The maximum dose of oxidronate sodium in adults is 2 mg.

Pediatric Patients

The recommended amount of radioactivity of Technetium Tc 99m Oxidronate Injection in pediatric patients is 7.4 MBq/kg to 13 MBq/kg (0.20 mCi/kg to 0.35 mCi/kg).

The recommended minimum and maximum activity in pediatric patients are 37 MBq (1 mCi) and 740 MBq (20 mCi), respectively. The maximum dose of oxidronate sodium in pediatric patients is 2 mg.

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Administration Instructions

- Measure the patient dose with a dose calibrator just prior to administration.
- Administer the dose intravenously by slow injection 1 hour to 4 hours before imaging.
- To minimize radiation dose to the bladder, encourage the patients to drink fluids before and after administration of Technetium Tc 99m Oxidronate Injection and to void immediately before the examination and as often thereafter as possible for the next 6 hours. (See **PRECAUTIONS, General**.)

Directions for Drug Preparation

Procedural Precautions

- The contents of the vial are intended only for use in the preparation of Technetium Tc 99m Oxidronate Injection and are NOT to be administered directly to the patient.
- The components of the kit are sterile and non-pyrogenic. Follow the directions carefully and adhere to strict aseptic procedures during preparation.
- Sodium pertechnetate Tc 99m injection that contains an oxidizing agent or 0.9% sodium chloride injection containing preservatives is not suitable for use in the preparation of Technetium Tc 99m Oxidronate Injection.
- Wear waterproof gloves during the entire preparation procedure and during subsequent patient dose withdrawals from the reaction vial.
- Make all transfers of sodium pertechnetate Tc 99m injection using an adequately shielded syringe.
- Keep the prepared Technetium Tc 99m Oxidronate Injection in the lead vial shield with fitted lead cover in place during the useful life of the radioactive preparation. Make all withdrawals and injection of the Technetium Tc 99m Oxidronate Injection with an adequately shielded syringe.
- If the dose is for a single adult patient or for pediatric patients, see Directions for the Preparation of a Single Adult Dose or Pediatric Dose(s).

Directions for the Preparation of Adult Doses

1. Remove the plastic disc from the Technescan HDP vial and swab the rubber septum with an alcohol swab or a suitable bacteriostatic agent to disinfect the surface.
2. Place the vial in a lead vial shield. Add 3 mL to 6 mL of sodium pertechnetate Tc 99m injection and secure with a fitted lead cover. In choosing the amount of sodium pertechnetate Tc 99m injection radioactivity to be used, the number of doses desired, the activity of each dose, and radioactive decay must be taken into account. The recommended maximum activity of sodium pertechnetate Tc 99m injection to be added to the vial is 11,100 MBq (300 mCi).
3. Shake the vial gently, for approximately 30 seconds, to ensure complete dissolution.
4. Using proper shielding, visually inspect the reaction vial. The resulting solution should be clear and free of particulate matter. If not, do not use the product.
5. Assay the product in a suitable dose calibrator and record the time, date of preparation, and the activity of the Technetium Tc 99m Oxidronate Injection on the radioassay information label and affix it to the vial.
6. Determine the radiochemical purity prior to administration.
7. Store the reaction vial upright in the lead vial shield with fitted lead cover in place at room temperature, 20°C to 25°C (68° to 77°F). Use within 8 hours of radiolabeling.
8. Dispose of unused material in a safe manner in accordance with applicable regulations.

Directions for the Preparation of a Single Adult Dose or Pediatric Dose(s)

a. Remove the plastic cap from the Technescan HDP vial and swab the rubber septum with an alcohol swab or a suitable bacteriostatic agent to disinfect the surface.
b. Add 3 mL to 6 mL of 0.9% sodium chloride injection. Shake the vial gently for approximately 30 seconds to assure complete dissolution.
c. Withdraw and discard all but approximately 1 mL of the solution.
d. Place the vial in a lead vial shield. Add an appropriate amount of sodium pertechnetate Tc 99m injection for a single adult dose or for one or more pediatric doses and shake gently. No more than 1,480 MBq (40 mCi) should be added to the vial when preparing multiple pediatric doses.
e. Proceed with steps 4 through 8 above.

Radiation Dosimetry

Estimated absorbed radiation doses from an intravenous injection of Technetium Tc 99m Oxidronate Injection are shown in Table 4.

HOW SUPPLIED

Technescan HDP (kit for the preparation of technetium Tc 99m oxidronate injection) contains 3.15 mg oxidronate sodium as a white lyophilized powder in a multiple-dose vial.

Technescan HDP is available as:

- 5 vials per carton (NDC 69945-091-20)
- 30 vials per carton (NDC 69945-091-40)

Before radiolabeling, store at 20°C to 25°C (68°F to 77°F) [see USP Controlled Room Temperature].

After radiolabeling, store vial upright in appropriate shielding at 20°C to 25°C (68°F to 77°F) [see USP Controlled Room Temperature]. Use within 8 hours of radiolabeling.

Dispose of unused products in accordance with appropriate regulations.

This reagent kit is for distribution to persons licensed by the U.S. Nuclear Regulatory Commission or the relevant regulatory authority of an Agreement State.

Table 4. Estimated Absorbed Radiation Doses in Organs and Tissues in Patients Who Received Technetium Tc 99m Oxidronate Injection

Organ/Tissue	Absorbed Dose* per Unit Activity Administered (mGy/MBq)				
	Adults	15 years	10 years	5 years	1 year
Adrenals	0.0021	0.0026	0.0038	0.0058	0.0110
Bone surfaces	0.0340	0.0150	0.0230	0.0380	0.0820
Brain	0.0017	0.0020	0.0028	0.0042	0.0059
Breast	0.0007	0.0009	0.0013	0.0021	0.0040
Gallbladder wall	0.0014	0.0018	0.0033	0.0043	0.0065
GI tract					
Stomach	0.0012	0.0014	0.0024	0.0036	0.0064
Small intestine wall	0.0022	0.0028	0.0043	0.0061	0.0093
Colon wall	0.0027	0.0034	0.0052	0.0072	0.0100
Upper large intestine wall	0.0019	0.0024	0.0038	0.0057	0.0087
Lower large intestine wall	0.0038	0.0047	0.0071	0.0092	0.0130
Heart	0.0012	0.0015	0.0022	0.0033	0.0059
Kidneys	0.0072	0.0087	0.0120	0.0180	0.0310
Liver	0.0012	0.0016	0.0024	0.0036	0.0064
Lungs	0.0012	0.0016	0.0023	0.0035	0.0067
Muscles	0.0018	0.0022	0.0033	0.0047	0.0077
Esophagus	0.0010	0.0013	0.0019	0.0029	0.0051
Ovaries	0.0036	0.0045	0.0065	0.0086	0.0120
Pancreas	0.0016	0.0020	0.0030	0.0045	0.0079
Red marrow	0.0059	0.0054	0.0088	0.0170	0.0360
Skin	0.0010	0.0013	0.0019	0.0030	0.0053
Spleen	0.0014	0.0018	0.0027	0.0044	0.0077
Testes	0.0024	0.0033	0.0054	0.0085	0.0100
Thymus	0.0010	0.0013	0.0019	0.0029	0.0051
Thyroid	0.0013	0.0015	0.0022	0.0034	0.0054
Urinary bladder wall	0.0470	0.0590	0.0870	0.1100	0.1300
Uterus	0.0062	0.0075	0.0110	0.0140	0.0180
Remaining organs	0.0019	0.0023	0.0034	0.0050	0.0077
Effective Dose (mSv/MBq)	**0.0049**	**0.0057**	**0.0086**	**0.0120**	**0.0180**

*For normal skeletal uptake and kidney function.

Manufactured by: Curium US LLC
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Made in USA

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