



MDP-25
Kit for the Preparation of Technetium Tc 99m Medronate Injection

CTD MODULE I – 1.14.1 Draft Labeling

1.14.1.3 Draft Labeling Text

The following pages provide a copy of the proposed package insert labeling for the new formulation of MDP-25, Kit for the Preparation of Technetium Tc 99m Medronate Injection. An electronic copy of the package insert is also provided with this application.



MDP-25
Kit for the Preparation of Technetium Tc 99m Medronate Injection

CTD MODULE I – 1.14.1 Draft Labeling

MDP-25

Kit for the Preparation of Technetium Tc 99m Medronate Injection

For Intravenous Use

DIAGNOSTIC – FOR SKELETAL IMAGING

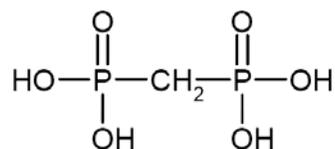
DESCRIPTION

The kit consists of reaction vials which contain the sterile, non-pyrogenic, non-radioactive ingredients necessary to produce Technetium Tc 99m Medronate Injection for diagnostic use by intravenous injection. MDP-25 reaction vials are intended to be used as multidose vials.

Each 10 mL MDP-25 reaction vial contains 25.0 mg medronic acid and not less than 2.75 mg of stannous chloride dihydrate (maximum total tin expressed as stannous chloride dihydrate 3.0 mg) and 5.0 mg of p-aminobenzoic acid in lyophilized form under an atmosphere of nitrogen.

The pH is adjusted to 6.8 to 6.9 with HCl or NaOH prior to lyophilization. The addition of sterile, non-pyrogenic, and oxidant-free sodium pertechnetate Tc 99m sterile solution produces a rapid labeling which is essentially quantitative and which remains stable in vitro throughout the 12-hours life of the preparation. No bacteriostatic preservative is present.

The structural formula of medronic acid is:



TMDRAXIMAGE, a division of DRAXIS Specialty Pharmaceuticals Inc.



MDP-25
Kit for the Preparation of Technetium Tc 99m Medronate Injection

CTD MODULE I – 1.14.1 Draft Labeling

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 %/ Disintegration	Energy (keV)
Gamma-2	89.07	140.5

EXTERNAL RADIATION

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

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.



MDP-25
Kit for the Preparation of Technetium Tc 99m Medronate Injection

CTD MODULE I – 1.14.1 Draft Labeling

¹Kocher, David C.: "Radioactive Decay Data Tables", DOE/TIC-11026, 108 (1981)

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

When injected intravenously, Technetium Tc 99m Medronate is rapidly cleared from the blood; about 50% of the dose is accumulated and retained by the skeleton, while the remaining 50% is excreted in the urine within 24 hours. About 10% of the injected dose remains in the blood at 1 hour post-injection, 5% at 2 hours, and less than 1% remains at 24 hours. The resultant blood clearance curve is tri-exponential with the two fastest components accounting for all but a few percent of the injected dose.

Following intravenous administration of Technetium Tc 99m Medronate, skeletal uptake occurs as a function of blood flow to bone and bone efficiency in extracting the complex. Bone mineral crystals are generally considered to be hydroxyapatite, and the complex appears to have an affinity for the hydroxyapatite crystals in the bone.

The rapid blood clearance provides bone to soft-tissue ratios which favor early imaging. The skeletal uptake is bilaterally symmetrical and is greater in the axial skeleton than in the long bones. Areas of abnormal osteogenesis show altered uptake making it possible to visualize a variety of osseous lesions.

INDICATIONS AND USAGE

MDP-25 (Kit for the Preparation of Technetium Tc 99m Medronate) may be used as a bone imaging agent to delineate areas of altered osteogenesis.



MDP-25
Kit for the Preparation of Technetium Tc 99m Medronate Injection

CTD MODULE I – 1.14.1 Draft Labeling

CONTRAINDICATIONS

None known at present.

WARNINGS

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

The contents of the kit before preparation are not radioactive. However, after the sodium pertechnetate Tc 99m is added, adequate shielding of the final preparation must be maintained.

Preliminary reports indicate impairment of brain images using sodium pertechnetate Tc 99m injection which have been preceded by bone imaging using an agent containing stannous ions. The impairment may result in false-positive or false-negative brain images. It is recommended, where feasible, that brain imaging using sodium pertechnetate Tc 99m injection precede bone imaging procedures. Alternatively, a brain imaging agent such as technetium Tc 99m pentetate may be employed.

PRECAUTIONS

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

To minimize the radiation dose to the bladder, the patient should be encouraged to increase fluid intake and to void as often as possible after the injection of Technetium Tc 99m Medronate, and for 4 to 6 hours after the imaging procedure.

The preparation contains no bacteriostatic preservative.

Both the powdered and reconstituted forms of MDP-25 should be stored at 25°C (77°F); excursions permitted between 15° and 30°C (59° to 86°F). The reconstituted product should be stored in a suitable lead shield. The solution should not be used if it is cloudy.

Optimal imaging results are obtained 1 to 4 hours after administration. The image quality may be adversely affected by obesity, old age and impaired renal function.



MDP-25
Kit for the Preparation of Technetium Tc 99m Medronate Injection

CTD MODULE I – 1.14.1 Draft Labeling

GENERAL

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 99m Medronate as well as other radioactive drugs must be handled with care. Once sodium pertechnetate Tc 99m is added to the vial, appropriate safety measures should be used to minimize external radiation to clinical occupational personnel. Care should also be taken to minimize radiation exposure to patients in a manner consistent with proper patient management.

The technetium Tc 99m labeling reactions involved depend on maintaining the stannous ion in the reduced state. Hence, sodium pertechnetate Tc 99m containing oxidants should not be employed.

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 or mutagenic potential or whether Technetium Tc 99m Medronate affects fertility in males or females.

PREGNANCY CATEGORY C

Animal reproduction and teratogenicity studies have not been conducted with Technetium Tc 99m Medronate. It is also not known whether Technetium Tc 99m Medronate can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. There have been no studies in pregnant women. Technetium Tc 99m should be given to a pregnant woman only if clearly needed.

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

NURSING MOTHERS



MDP-25
Kit for the Preparation of Technetium Tc 99m Medronate Injection

CTD MODULE I – 1.14.1 Draft Labeling

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

PEDIATRIC USE

Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS

Several cases of allergic dermatological reactions have been reported in association with the use of Technetium Tc 99m Medronate.

Several reactions have also been reported in association with other radiopharmaceuticals of the diphosphonate class, particularly Technetium Tc 99m Medronate. These are usually hypersensitivity reactions characterized by itching, various skin rashes, hypotension, chills, nausea, fever, and vomiting. One death secondary to cardiac arrhythmia following the administration of Technetium Tc 99m Medronate has been reported. In addition, one case of cardiac arrest in a patient also undergoing pulmonary function testing one and one-half hours after the performance of a bone scan using Technetium Tc 99m Medronate has been reported.

DOSAGE AND ADMINISTRATION

The recommended adult dose, after reconstitution with oxidant-free sodium pertechnetate Tc 99m, is 370 to 740 megabecquerels (10 to 20 millicuries [200 μ Ci/kg]) by slow intravenous injection over a period of 30 seconds. Optimum scanning time is 1 to 4 hours post-injection.

To minimize the contribution of the bladder content to the image, the patient should void immediately before imaging is started.

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

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. The solution should not be used if cloudy.

RADIATION DOSIMETRY



MDP-25
Kit for the Preparation of Technetium Tc 99m Medronate Injection

CTD MODULE I – 1.14.1 Draft Labeling

The estimated absorbed radiation doses to an average patient (70 kg) from an intravenous injection of a maximum dose of 740 megabecquerels (20 millicuries) of Technetium Tc 99m Medronate are shown in Table 4. The effective half-life was assumed to be the physical half-life for all calculated values.

Table 4
RADIATION DOSES²

Tissue	Absorbed Radiation Dose	
	mGy/740 MBq	rads/20 mCi
Total Body	1.3	0.13
Total Bone	7.0	0.70
Red Marrow	5.6	0.56
Kidneys	8.0	0.80
Liver	0.6	0.06
Bladder Wall		
2 hr. void	26.0	2.60
4.8 hr. void	62.0	6.20
Ovaries		
2 hr. void	2.4	0.24
4.8 hr. void	3.4	0.34
Testes		
2 hr. void	1.6	0.16
4.8 hr. void	2.2	0.22

²Method of calculation: “S” Absorbed Dose per Unit Cumulated Activity for Selected Radionuclides and Organs, MIRD Pamphlet No. 11, 1975

HOW SUPPLIED

MDP-25,
Kit for the Preparation of Technetium Tc 99m Medronate Injection
Product No. 500661 (5 vials), 500663 (30 vials) or 500666 (100 vials)

Available in boxes consisting of 5, 30 or 100 reaction vials, each vial containing in lyophilized form, sterile and non-pyrogenic:



MDP-25
Kit for the Preparation of Technetium Tc 99m Medronate Injection

CTD MODULE I – 1.14.1 Draft Labeling

Medronic Acid	25.0 mg
Stannous Chloride Dihydrate (minimum)	2.0 mg
(Maximum tin as stannous chloride dihydrate)	3.0 mg
p-Aminobenzoic Acid	5.0 mg

The pH is adjusted to 6.8 to 6.9 with HCl or NaOH prior to lyophilization. The vials are sealed under an atmosphere of nitrogen.

Radioassay information labels with radiation warning symbol and a package insert are supplied in each box.

STORAGE

Store the unreconstituted reaction vials at 25°C (77°F); excursions permitted between 15° and 30°C (59° to 86°F). After labeling with Technetium Tc 99m, the reconstituted product should be stored at 25°C (77°F) in the original vial, and be placed in a suitable lead shield. Excursions permitted between 15° and 30°C (59° to 86°F). Discard the reconstituted solution after 12 hours.

DIRECTIONS

NOTE: Use aseptic procedures throughout and take precautions to minimize radiation exposure by use of suitable shielding. Use waterproof gloves during the following preparation procedure.

MDP-25 reaction vials are intended for the preparation of multiple doses of technetium Tc-99m medronate and the entire contents of the vial should not be used as a single dose.

Before reconstituting a vial, it should be inspected for cracks and/or a melted plug or any other indication that the integrity of the vacuum seal has been compromised.

To prepare Technetium Tc 99m Medronate:

1. Remove the central metal disc from a reaction vial and swab the closure with either an alcohol swab or a suitable bacteriostatic agent.
2. Place the reaction vial in a suitable lead vial shield (minimum wall thickness 1/8 inch) which has a fitted lead cap. Obtain 2 to 10 mL of sterile, non-pyrogenic sodium pertechnetate Tc 99m, using a shielded syringe.



MDP-25
Kit for the Preparation of Technetium Tc 99m Medronate Injection

CTD MODULE 1 – 1.14.1 Draft Labeling

The recommended **maximum amount** of Technetium Tc 99m to be added to a reaction vial is 37.0 gigabecquerels (1000 mCi). Sufficient sodium pertechnetate is to be used for the reconstitution of a reaction vial to ensure that the dose of medronate administered does not exceed 10 mg. Sodium pertechnetate Tc 99m solutions containing an oxidizing agent are not suitable for use.

3. Using a shielded syringe, add the sodium pertechnetate Tc 99m solution to the reaction vial aseptically.
4. Place the lead cap on the reaction vial shield and agitate the shielded reaction vial until the contents are completely dissolved. The solution must be clear and free of particulate matter before proceeding.
5. Assay the product in a suitable calibrator, record the radioassay information on the label with radiation warning symbol, and apply it to the reaction vial.
6. Withdrawals for administration must be made aseptically using a shielded sterile syringe and needle. Since the reaction vials contain nitrogen to prevent oxidation of the complex, they should not be vented. If repeated withdrawals are made, minimize the replacement of contents with room air.



MDP-25
Kit for the Preparation of Technetium Tc 99m Medronate Injection

CTD MODULE I – 1.14.1 Draft Labeling

The following steps should be followed to ensure that each reconstituted of technetium Tc 99m medronate contains between 1 and 10 mg of medronic acid.

Where:

V_r = Final volume of in the vial in mL after reconstitution.

C = Concentration of Medronic Acid in mg/mL.

Max. V = Maximum volume to be used for one dose in mL.

Min. V = Minimum volume to be used for one dose in mL.

a) Prior to reconstitution, determine the radioactive concentration of the sodium pertechnetate Tc 99m.

b) Note the volume and activity added to the vial. It should be between 1.85 – 37.0 GBq (50 – 1000 mCi) in 1 to 10 mL.

c) Calculate the concentration (C) of Medronic acid in the vial after reconstitution.

$$C \text{ (mg/mL)} = 25 \text{ mg} \div V_r \text{ (mL)}$$

d) To ensure that the dose contains a maximum of 10 mg, the following formula should be used to calculate the maximum volume (Max. V) to be dispensed as one dose.

$$\text{Max. V (mL)} = 10 \text{ mg} \div C \text{ (mg/mL)}$$

e) To ensure that a minimum dose of 1 mg is dispensed, the following formula should be used to calculate the minimum volume (Min. V) to be dispensed as one dose

$$\text{Min. V} = 1 \div C$$

7. The finished preparation should be stored at 25°C (77°F); excursions permitted between 15° and 30°C (59° to 86°F) when not in use and discarded after 12 hours. It should also be stored during its life in a suitable lead shield.

This reagent kit is approved by the U.S. Nuclear Regulatory Commission for distribution to persons licensed to use by-product material identified in §35.200 to 10 CFR Part 35, to persons who have a similar authorization issued by an Agreement State, and, outside the United States, to persons authorized by the appropriate authority.



MDP-25
Kit for the Preparation of Technetium Tc 99m Medronate Injection

CTD MODULE I – 1.14.1 Draft Labeling

NDC 65174-640-xx (5 vials)
NDC 65174-660-xx (30 vials)
NDC 65174-680-xx (100 vials)

Manufactured by:
DRAXIMAGE, a division of DRAXIS Specialty Pharmaceuticals Inc.
Kirkland, Quebec H9H 4J4 Canada

Printed in Canada

Issued Date



MDP-25
Kit for the Preparation of Technetium Tc 99m Medronate Injection

CTD MODULE I – 1.14.1 Draft Labeling

1.14.1 Draft Labeling

1.14.1.1 Draft Carton and Container Labels

A. Proposed MDP-25 new formulation and Approved MDP-25 Vial Labeling

Below find a copy of the proposed vial labeling for the new formulation of MDP-25 with changes highlighted in comparison with the currently approved vial labeling for MDP-25, Kit for the Preparation of Technetium Tc 99m Medronate Injection manufactured by DRAXIMAGE, a division of DRAXIS Specialty Pharmaceuticals Inc. Kirkland, Québec, Canada.

In accordance with 21 CFR 201.10 (i) (1) (i-iv) information related to the ingredients, the established name of the drug, lot number, and name of the manufacturer are provided. Complete labeling information as required by section 502 (e) of the Food Drug and Cosmetic Act, can be found on the post-reconstitution labeling found on the exterior of the lead-shielding for the labeled product and on the package labeling (cartons).

MDP-25
(Proposed new
formulation vial
label)

MULTIDOSE VIAL	Rx Only
Sterile, Non-pyrogenic	
DRAXIMAGE® MDP-25	
Kit for the Preparation of Technetium Tc 99m Medronate Injection	
Diagnostic – for Skeletal Imaging	
Each reaction	Medronic Acid 25.0 mg
vial contains:	Stannous Chloride Dihydrate (Minimum)..... 2.0 mg
	(Max. tin as stannous chloride dihydrate)..... 3.0 mg)
	p-Aminobenzoic Acid..... 3.0 mg
pH adjusted to 6.8 to 6.9 with HCl and/or NaOH prior to lyophilization. Sealed under nitrogen.	
Contains No Bacteriostatic Preservative. For Intravenous Use Only	
Before reconstitution and after labeling with oxidant-free Technetium Tc 99m, store at 25°C (77°F).	
After labeling store in a suitable lead shield and use within 12 hours.	
Recommended Adult Dose : 370-740 megabecquerels (10-20 mCi)	
SEE PACKAGE INSERT	
DRAXIMAGE, a division of DRAXIS Specialty Pharmaceuticals Inc.	
Kirkland, Québec, Canada	Printed in Canada

MDP-25
(Currently approved
vial label)

MULTIDOSE VIAL	Rx Only
Sterile, Non-pyrogenic	
DRAXIMAGE® MDP-25	
Kit for the Preparation of Technetium Tc 99m Medronate Injection	
Diagnostic – for Skeletal Imaging	
Each reaction	Medronic Acid 25 mg
vial contains:	Stannous Chloride..... 0.8 mg
	(Max. tin as stannous chloride dihydrate)..... 1.2 mg)
	p-Aminobenzoic Acid..... 2 mg)
pH adjusted to 6.5 to 7.5 with HCl and/or NaOH prior to lyophilization. Sealed under nitrogen.	
Contains No Bacteriostatic Preservative. For Intravenous Use Only	
Before reconstitution and after labeling with oxidant-free Technetium Tc 99m, store at 25°C (77°F).	
After labeling store in a suitable lead shield and use within 12 hours.	
Recommended Adult Dose : 370-740 megabecquerels (10-20 mCi)	
(SEE PACKAGE INSERT)	
DRAXIMAGE Inc.	
Printed in Canada	Kirkland, Québec, Canada



MDP-25
 Kit for the Preparation of Technetium Tc 99m Medronate Injection

CTD MODULE I – 1.14.1 Draft Labeling

B. Proposed Post-Reconstitution Labeling

Provided below is a copy of the proposed post-reconstitution labeling for MDP-25 new formulation, Kit for the Preparation of Technetium Tc 99m Medronate Injection.

Please note that the only difference between the proposed and the approved labeling is the change of the company's name which is DRAXIMAGE, a division of DRAXIS Specialty Pharmaceuticals Inc. instead of DRAXIMAGE Inc. Complete labeling information for this product as required by section 502 (e) of the Food Drug and Cosmetic Act is provided on this labeling.

Total Activity _____ MBq _____ mCi Volume _____ mL Concentration _____ MBq/mL _____ mCi/mL As of _____ Expiry _____	Technetium Tc 99m Medronate Injection Diagnostic – for skeletal imaging
After labeling with oxidant-free Technetium Tc 99m, store at 25°C (77°F) in a suitable lead shield and use within 12 hours; See Package Insert.	 Usual Adult Dose: 370 to 740 Megabecquerels (10 to 20 millicuries) of Technetium Tc 99m Medronate Injection See Package Insert CAUTION: Federal (USA) law prohibits dispensing without prescription Product Code DRAXIMAGE, a division of DRAXIS Specialty Pharmaceuticals Inc. Kirkland, Quebec, Canada
FOR INTRAVENOUS USE	



MDP-25
Kit for the Preparation of Technetium Tc 99m Medronate Injection

CTD MODULE 1 – 1.14.1 Draft Labeling

Proposed Box of 5 vials for MDP-25 New formulation

Lot: Exp:	<p>CAUTION: Federal (USA) law prohibits dispensing without prescription. FOR INTRAVENOUS USE AFTER LABELING WITH OXIDANT-FREE TECHNETIUM Tc 99m. <i>After labeling with Technetium Tc 99m, store the solution at 25°C (77°F); excursions permitted between 15 and 30°C (59 to 86°F) and use within 12 hours.</i></p>	
	<p>No. XXXXXX</p> <p>DRAX IMAGE®</p> <p>MDP-25</p> <p>Kit for the Preparation of Technetium Tc 99m Medronate Injection</p> <p>Diagnostic – for skeletal imaging</p> <p><small>DRAXIMAGE, a division of DRAXIS Specialty Pharmaceuticals Inc. Kirkland Quebec H9H 4J4 Canada</small></p>	<p>MDP-25</p> <p>Kit for the Preparation of Technetium Tc 99m Medronate Injection</p> <p>Diagnostic – for skeletal imaging</p>
	<p>Recommended Adult Dose: 370 to 740 megabecquerels (10 to 20 millicuries). See enclosed package insert.</p> <p>KIT CONTAINS: 5 reaction vials each containing sterile and non-pyrogenic 25.0 mg of Medronic Acid and 2.0 mg (minimum) Stannous Chloride Dihydrate (maximum tin expressed as stannous chloride dihydrate 3.0 mg) and 5.0 mg of p-Aminobenzoic Acid. The pH is adjusted to 6.8 to 6.9 with HCL and/or NaOH prior to lyophilization. Sealed under nitrogen.</p> <p>5 radioassay information labels with radiation warning symbol.</p> <p>1 package insert.</p> <p>CONTAINS NO BACTERIOSTATIC PRESERVATIVE</p> <p>Printed in Canada</p>	



MDP-25
Kit for the Preparation of Technetium Tc 99m Medronate Injection

CTD MODULE 1 – 1.14.1 Draft Labeling

Currently approved Box of 5 vials for MDP-25

<p>Lot: Exp:</p>	<p>CAUTION: Federal (USA) law prohibits dispensing without prescription. FOR INTRAVENOUS USE AFTER LABELING WITH OXIDANT-FREE TECHNETIUM Tc 99m. <i>After labeling with Technetium Tc 99m, store the solution at 25°C (77°F); excursions permitted between 15 and 30°C (59 to 86°F) and use within 12 hours.</i></p> <p>No. XXXXXX</p> <p style="text-align: center;">DRAXIMAGE[™]</p> <p style="text-align: center;">MDP-25</p> <p style="text-align: center;">Kit for the Preparation of Technetium Tc 99m Medronate Injection</p> <p style="text-align: center;">Diagnostic – for skeletal imaging</p> <p style="text-align: right;">DRAXIMAGE Inc. Kirkland Québec H9H 4J4 Canada</p>	<p>MDP-25</p> <p>Kit for the Preparation of Technetium Tc 99m Medronate Injection Diagnostic – for skeletal imaging</p>
<p>Recommended Adult Dose: 370 to 740 megabecquerels (10 to 20 millicuries). See enclosed package insert.</p> <p>KIT CONTAINS: 5 reaction vials each containing sterile and non-pyrogenic 25.0 mg of Medronic Acid and 0.8 mg (minimum) Stannous Chloride Dihydrate (maximum tin expressed as stannous chloride dihydrate 1.2 mg) and 5.0 mg of p-Aminobenzoic Acid. The pH is adjusted to 6.5 to 7.5 with HCL and/or NaOH prior to lyophilization. Sealed under nitrogen. 5 radioassay information labels with radiation warning symbol. 1 package insert.</p> <p style="text-align: center;">CONTAINS NO BACTERIOSTATIC PRESERVATIVE</p> <p style="text-align: right;">Printed in Canada</p>		



MDP-25
Kit for the Preparation of Technetium Tc 99m Medronate Injection

CTD MODULE I – 1.14.1 Draft Labeling

Proposed Box of 30 vials for MDP-25 New formulation

<p>No. xxxx</p> <p>DRAX IMAGE[®]</p> <p>MDP-25</p> <p>Kit for the Preparation of Technetium Tc 99m Medronate Injection</p>	
<hr/> <p>DIAGNOSTIC – For skeletal imaging</p>	<p>Recommended Adult Dose: 370 to 740 megabecquerels (10 to 20 millicuries). See enclosed package insert.</p>
<hr/> <p>FOR INTRAVENOUS USE AFTER LABELING WITH OXIDANT-FREE TECHNETIUM Tc 99m</p>	<hr/> <p>KIT CONTAINS:</p>
<hr/> <p>CAUTION: Federal (USA) law prohibits dispensing without prescription</p>	<p>30 reaction vials each containing sterile and non-pyrogenic 25.0 mg of Medronic Acid and 2.0 mg (minimum) Stannous Chloride Dihydrate (maximum tin expressed as stannous chloride dihydrate 3.0 mg) and 5.0 mg of p-Aminobenzoic Acid. The pH is adjusted to 6.8 to 6.9 with HCL and/or NaOH prior to lyophilization. Sealed under nitrogen.</p>
<hr/> <p>Store the unreconstituted reaction vials at 25°C (77°F); excursions permitted between 15 and 30°C (59 to 86°F). After labeling with Technetium Tc 99m, store the solution at 25°C (77°F); excursions permitted between 15 and 30°C (59 to 86°F) and use within 12 hours.</p>	<p>30 radioassay information labels with radiation symbol.</p> <p>1 package insert</p>
<hr/> <p>DRAXIMAGE, a division of DRAXIS Specialty Pharmaceuticals Inc. Kirkland Québec H9H 4J4 Canada</p>	<hr/> <p>CONTAINS NO BACTERIOSTATIC PRESERVATIVE</p>



MDP-25
Kit for the Preparation of Technetium Tc 99m Medronate Injection

CTD MODULE I – 1.14.1 Draft Labeling

Currently approved Box of 30 vials for MDP-25

No. 500660

DRAX IMAGE™

MDP-25

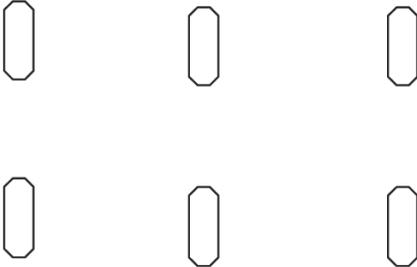
**Kit for the Preparation
of Technetium Tc 99m
Medronate Injection**

DIAGNOSTIC – For skeletal imaging

FOR INTRAVENOUS USE AFTER
LABELING WITH OXIDANT-FREE
TECHNETIUM Tc 99m

CAUTION: Federal (USA) law prohibits
dispensing without prescription

**Store the unconstituted reaction vials at
25°C (77°F); excursions permitted between
15 and 30°C (59 to 86°F). After labeling with
Technetium Tc 99m, store the solution at
25°C (77°F); excursions permitted between
15 and 30°C (59 to 86°F)**



◀ PINCH AT CORNERS / PULL OUT ▶

™ Trademark DRAXIMAGE Inc.

Recommended Adult Dose:
370 to 740 megabecquerels
(10 to 20 millicuries)
(see enclosed package insert)

KIT CONTAINS:
30 reaction vials each containing
sterile and non-pyrogenic
25 mg Medronic Acid and
0.8 mg (minimum) Stannous
Chloride Dihydrate (maximum)
Tin expressed as stannous
Chloride dehydrate 1.21 mg)
And 2 mg of p-Aminobenzoic
Acid. The pH is adjusted to
6.5 to 7.5 with HCl or NaOH
prior to lyophilization. Sealed
under nitrogen.

30 radioassay information labels
with radiation symbol.

1 package insert

CONTAINS NO BACTERIOSTATIC
PRESERVATIVE



MDP-25
Kit for the Preparation of Technetium Tc 99m Medronate Injection

CTD MODULE I – 1.14.1 Draft Labeling

Proposed Tray of 100 vials for MDP-25 New formulation

Side 1

No. xxxx

DRAX IMAGE

MDP-25

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

DIAGNOSTIC – For skeletal imaging

FOR INTRAVENOUS USE AFTER
LABELING WITH OXIDANT-FREE
TECHNETIUM Tc 99m

CAUTION: Federal (USA) law prohibits dispensing without prescription

Store the unconstituted reaction vials at 25°C (77°F); excursions permitted between 15 and 30°C (59 to 86°F). After labeling with Technetium Tc 99m, store the solution at 25°C (77°F); excursions permitted between 15 and 30°C (59 to 86°F) and use within 12 hours.

DRAXIMAGE, a division of DRAXIS Specialty Pharmaceuticals Inc.

Side 2

Recommended Adult Dose: 370 to 740 megabecquerels (10 to 20 millicuries)

See enclosed package insert

KIT CONTAINS:

100 reaction vials each containing sterile and non-pyrogenic 25.0 mg Medronic Acid and 2.0 mg (minimum) Stannous Chloride Dihydrate, (maximum) Tin expressed as stannous Chloride dihydrate 3.0 mg) and 5.0 mg of p-Aminobenzoic acid. The pH is adjusted to 6.8 to 6.9 with HCl and/or NaOH prior to lyophilization. Sealed under nitrogen.

100 radioassay information labels with radiation symbol.

1 package insert

CONTAINS NO BACTERIOSTATIC PRESERVATIVE

Printed in Canada



MDP-25
Kit for the Preparation of Technetium Tc 99m Medronate Injection

CTD MODULE 1 – 1.14.1 Draft Labeling

Side 3



Side 4





MDP-25
Kit for the Preparation of Technetium Tc 99m Medronate Injection

CTD MODULE I – 1.14.1 Draft Labeling

Currently approved Tray of 100 vials for MDP-25 (not marketed)

Side 1

No. 5006xx

DRAX+IMAGE™

MDP-25

**Kit for the Preparation of
Technetium Tc 99m
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DIAGNOSTIC – For skeletal imaging

FOR INTRAVENOUS USE AFTER
LABELING WITH OXIDANT-FREE
TECHNETIUM Tc 99m

CAUTION: Federal (USA) law prohibits dispensing without prescription

Store the unreconstituted reaction vials at 25°C (77°F); excursions permitted between 15 and 30°C (59 to 86°F). After labeling with Technetium Tc 99m, store the solution at 25°C (77°F); excursions permitted between 15 and 30°C (59 to 86°F) and use within 12 hours.

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Side 2

Recommended Adult Dose: 370 to 740 megabecquerels
(10 to 20 millicuries)

See enclosed package insert

KIT CONTAINS:

100 reaction vials each containing sterile and non-pyrogenic 25.0 mg Medronic Acid and 0.8 mg (minimum) Stannous Chloride Dihydrate, (maximum) Tin expressed as stannous Chloride dihydrate 1.2 mg) and 2.0 mg of p-Aminobenzoic acid. The pH is adjusted to 6.5 to 7.5 with HCl and/or NaOH prior to lyophilization. Sealed under nitrogen.

100 radioassay information labels with radiation symbol.

1 package insert

CONTAINS NO BACTERIOSTATIC PRESERVATIVE

Printed in Canada