PRODUCT MONOGRAPH

Ultratag™ RBC

Kit for the Preparation of Technetium Tc 99m-Labeled Red Blood Cells Solution, 10 to 20 mCi per vial

Radiodiagnostic Agent

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Distributed by:
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CANADA

CURIUM™

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Ultratag™ RBC
Kit for the Preparation of Technetium Tc 99m-Labeled Red Blood Cells

PART I: HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

Route of Administration	Dosage Form / Strength	Clinically Relevant Non-medicinal Ingredients
Intravenous injection	Solution, 10 to 20 mCi per vial	Reaction vial contains: dextrose anhydrous, sodium citrate dihydrate, tin chloride (stannous and stannic) dihydrate Syringe I contains: sodium hypochlorite Syringe II contains: citric acid monohydrate, dextrose anhydrous, sodium citrate dihydrate *For a complete listing see Dosage Forms, Composition and Packaging section.*

DESCRIPTION

Each kit consists of three separate non-radioactive components:

1. Reaction vial (10 milliliter) containing:

    - Stannous chloride, dihydrate ($SnCl_2 \bullet 2H_2O$) 50 µg minimum, 96 µg theoretical
    - Tin chloride (stannous and stannic) dihydrate, as stannous chloride ($SnCl_2 \bullet 2H_2O$) - 105 µg maximum
    - Sodium citrate, dihydrate - 3.67 mg
    - Dextrose, anhydrous - 5.50 mg

Prior to lyophilization, the pH is adjusted to 7.1 - 7.2 with sodium hydroxide. The contents of the vial are lyophilized and stored under argon.

2. Syringe I contains:

    - Sodium hypochlorite - 0.6 mg in sterile water for injection

The total volume of this syringe is 0.6 mL. Sodium hydroxide may have been added for pH adjustment. The pH of this solution is 11 - 13.

3. Syringe II contains:

- Citric acid, monohydrate - 8.7 mg
- Sodium citrate, dihydrate - 32.5 mg
- Dextrose, anhydrous - 12.0 mg in sterile water for injection

The total volume of this syringe is 1.0 mL. The pH range of this solution is adjusted to 4.5 - 5.5 with sodium citrate or citric acid.

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 is listed in Table 1.

Table 1. Principal Radiation Emission Data[1]

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

External Radiation

The specific gamma ray constant for technetium Tc 99m is 0.78 R/mCi-hr at 1 cm. The first half-value thickness of lead (Pb) for technetium Tc 99m is 0.017 cm. A range of values for the relative attenuation of the radiation emitted by radionuclide resulting from the interposition of various thicknesses of lead (Pb) is presented in Table 2. For example, the use of 0.25 cm of lead will decrease the external radiation exposure by a factor of about 1000.

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 presented in Table 3.

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

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

* Calibration time

INDICATIONS AND CLINICAL USE

Technetium Tc 99m Red Blood Cells are used for blood pool imaging, including cardiac first pass and gated equilibrium imaging, and for detection of sites of gastrointestinal bleeding.

CONTRAINDICATIONS

None known.

However, patients who are hypersensitive to this drug or to any ingredient in the formulation or component of the container should advise their physician. For a complete listing, see **DOSAGE FORMS, COMPOSITION AND PACKAGING**.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

Radiopharmaceuticals should be used under the supervision of 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.

General
The product should be administered under the supervision of a physician who is experienced in the use of radiopharmaceuticals. Appropriate management of therapy and complications is only possible when adequate diagnostic and treatment facilities are readily available.

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

The labeled red blood cells must be re-injected into the patient from whom the blood was drawn.

The contents of the kit are intended only for use in the preparation of Technetium Tc 99m Red Blood Cells and are NOT to be administered directly to the patient.

The contents of this kit are not radioactive. After sodium pertechnetate Tc 99m is added, however, adequate shielding of the preparation must be maintained.

Technetium Tc 99m Red Blood Cells must be handled with care to ensure minimum radiation exposure to the patient, consistent with proper patient management, and to ensure minimum radiation exposure to occupational workers.

Clinical trials to study the effect of concomitant medication on the *in vitro* labeling efficiency of the Ultratag™ RBC kit showed that heparin, methyldopa, quinidine, hydralazine, prazosin, digoxin and lidocaine had no significant effect on the labeling efficiency. It is recommended that the labeled red blood cells be administered within 30 minutes of preparation or as soon as possible thereafter. A small study has shown that Technetium Tc 99m-Labeled Red Blood Cells prepared with Ultratag™ RBC have equivalent *in vivo* labeling efficiency when administered both immediately after preparation (5 patients studied) and at 6 hours after preparation (6 patients studied) with a 24-hour labeling efficiency averaging 97% for both groups.

Nuclear medicine procedures involving withdrawal and reinjection of blood have the potential for transmission of blood borne pathogens. Procedure should be implemented to avoid administration errors and viral contamination of personnel during blood product labeling. A system of checks similar to the ones used for administering blood transfusions should be routine.

Carcinogenesis and Mutagenesis
No long term animal studies have been performed to evaluate carcinogenic or mutagenic potential or to determine the effects on male or female fertility.

Contamination
The following measures should be taken for up to 12 hours after receiving the radiopharmaceutical product: Toilet should be used instead of urinal. Toilet should be flushed several times after use.

Special precautions such as bladder catheterization should be taken following administration to incontinent patients to minimize the risk of radioactive contamination of clothing, bed linen and the patient's environment.

Special Populations

Pregnant Women
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.

Animal reproduction studies have not been conducted with Technetium Tc 99m Red Blood Cells. It is also not known whether this drug can cause fetal harm when administered to a pregnant woman, or can affect reproductive capacity. Technetium Tc 99m Red Blood Cells should be administered to a pregnant woman only if clearly indicated.

Nursing Women
Technetium Tc 99m is excreted in human milk during lactation. Therefore, formula feeding should be substituted for breastfeeding for at least four hours after administration of Tc 99m labeled red blood cells.

Pediatrics (0 – 16 years of age)
Safety and efficacy in children have not been established.

Geriatrics (> 65 years of age)
No data available.

ADVERSE REACTIONS

None known.

DRUG INTERACTIONS

No data available.

DOSAGE AND ADMINISTRATION

The instructions for preparation must be carefully followed for preparing Technetium Tc 99m Red Blood Cells using Ultratag™ RBC kit.

The suggested dose range of Technetium Tc 99m Red Blood Cells in the average patient (70 kg) is 370 MBq (10 mCi) to 740 MBq (20 mCi).

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Aseptic procedures and a shielded syringe should be employed in preparing and withdrawing doses for administration to patients. The user should wear waterproof gloves during the administration procedure.

Administration

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

Instructions for Preparation and Use

The user should adhere to strict observance of aseptic technique procedures throughout the labeling procedure.

The components of the reagent vial are sterile and non-pyrogenic. It is essential that the user follows the directions carefully and adheres to strict aseptic technique.

Make all transfers of radioactive solutions with an adequately shielded syringe and maintain adequate shielding around the vial during the useful life of the radioactive product.

1. Collect patient's blood sample (1.0 to 3.0 mL) using heparin or ACD as an anticoagulant. The amount of ACD should not exceed 0.15 mL per mL of blood. The recommended amount of heparin is 10 - 15 units per mL of blood. DO NOT USE EDTA OR OXALATE AS AN ANTICOAGULANT.

2. To prevent damaging the cells, it is recommended to carefully withdraw and expel the blood via syringe and needle. Using a large-bore (19 to 21 gauge) needle, transfer 1.0 to 3.0 mL of anticoagulated whole blood to the reaction vial and gently mix to dissolve the lyophilized material for five minutes at ambient temperature.

3. Add the contents of syringe I to the reaction vial, incubate, and mix by gentle inversion four to five times.

4. Add the contents of syringe II to the reaction vial. Mix by gently inverting four to five times.

5. Place the vial in a lead shield fitted with a lead cap and having a minimum wall thickness of 3 mm. Add 370 - 3700 MBq (10 - 100 mCi) sodium pertechnetate Tc 99m injection (in a volume of up to 3 mL) to the reaction vial. The avoidance of long technetium Tc 99m in-growth times and the use of fresh sodium pertechnetate Tc 99m generator eluate are recommended, as Tc 99m decays to Tc 99 with a half-life of 6 hours.

6. Mix by gently inverting reaction vial four to five times. Allow to react for 20 minutes with occasional mixing.

7. Technetium Tc 99m Red Blood Cells should be injected within 30 minutes of preparation.

8. Assay labeling efficiency immediately prior to injection. Typical labeling efficiency is greater than 95%.

9. Mix gently prior to withdrawal of the patient dose. Aseptically transfer the Technetium Tc 99m Red Blood Cells to a syringe for administration to the patient. Use the largest bore needle compatible with patient administration to prevent hemolysis.

10. Assay the Tc 99m Red Blood Cells patient dose in a suitable calibrator and complete the radioassay information label. Affix the radioassay information label to the shield.

NOTES:
The kit does not contain an anticoagulant. Therefore, a syringe or Vacutainer™ tube treated with ACD or heparin must be used for drawing the patient's blood. The amount of ACD should not exceed 0.15 mL of ACD per mL of blood. The recommended amount of heparin is 10 to 15 units per mL of blood. Improper anticoagulated blood will be unsuitable for re-injection.

Vacutainer is a trademark of Becton Dickinson and Company.

Directions for Quality Control
The radiochemical purity of the radiopharmaceutical product should be determined prior to administration to the patient.

The labeling yield determination can be carried out as follow:

Transfer 0.2 mL of the Technetium Tc 99m Red Blood Cells to a centrifuge tube containing 2 mL of sodium chloride 0.9%. Centrifuge for five minutes at 2000 r.p.m. and carefully pipet off the diluted plasma. Measure the radioactivity in the plasma and red blood cells separately in a suitable counter. Calculate the labeling efficiency as follows:

$$\% \text{ RBC Labeling} = \frac{\text{RBC Activity}}{\text{RBC Activity + Plasma Activity}} \times 100$$

RADIATION DOSIMETRY

The absorbed radiation doses[2] to an average adult (70 kg) from an intravenous injection of a maximum dose of 740 MBq (20 mCi) of Technetium Tc 99m Red Blood Cells are shown in Table 4. The estimated fetal absorbed radiation doses[3] for a maximum dose of 20 mCi of Technetium Tc 99m Red Blood Cells are shown in Table 5.

Table 4. Absorbed Radiation Dose[2] for for Technetium Tc 99m-Labeled Red Blood Cells

Organ	**mGy/740 MBq**	**rad/20 mCi**
Adrenals	7.3	0.73
Bladder	6.3	0.63
Bone surfaces	5.5	0.55
Brain	2.7	0.27
Breast	2.6	0.26
Gall bladder	4.8	0.48
Stomach	3.4	0.34
Small Intestines	2.9	0.29
Colon	2.7	0.27
Upper Large Intestines (ULI)	3.0	0.30
Lower Large Intestines (LLI)	2.5	0.25
Heart	17	1.7
Kidneys	13	1.3
Liver	9.6	0.96
Lungs	13	1.3
Muscles	2.4	0.24
Esophagus	4.5	0.45
Ovaries	2.7	0.27
Pancreas	4.9	0.49
Red marrow	4.5	0.45
Skin	1.5	0.15
Spleen	10	1.0
Testes	1.7	0.17
Thymus	4.5	0.45
Thyroid	4.2	0.42
Uterus	2.9	0.29
Remaining organs	2.6	0.26
Effective Dose Equivalent	**5.2 mSv/740 MBq**	**0.52 rem/20 mCi**

Table 5. Fetal Absorbed Radiation Doses Estimates [3] from a 20 mCi dose of Technetium Tc 99m-Labeled Red Blood Cells

Stage of Gestation	Fetal Dose mGy/MBq (rad/mCi)	Fetal Dose mGy (rad)
Early	0.0068 (0.025)	5.0 (0.50)
3 months	0.0047 (0.017)	3.5 (0.35)
6 months	0.0034 (0.012)	2.5 (0.25)
9 months	0.0028 (0.010)	2.1 (0.21)

OVERDOSAGE

No data available.

ACTION AND CLINICAL PHARMACOLOGY

In vitro Tc 99m red blood cell labeling is accomplished by adding 1.0 - 3.0 milliliters of autologous whole blood, anti-coagulated with heparin or anticoagulant citrate dextrose solution USP (ACD), to the reaction vial. A portion of the stannous ions in the reaction vial diffuses across the red blood cell membrane and accumulates intracellularly. The *in vitro* Tc 99m red blood cell labeling efficiency can decrease in the presence of excess ACD. Excess ACD apparently impairs the diffusion of stannous ion across the red blood cell membrane. Therefore, the ACD concentration used for blood collection should not exceed 0.15 mL ACD per mL of blood. Sodium hypochlorite is then added to the reaction vial to oxidize the extracellular stannous ion[4]. Since the hypochlorite does not cross the red blood cell membrane, the oxidation of stannous ion is selective for the extracellular tin. A citric acid, sodium citrate and dextrose solution is then added to the reaction vial to sequester any residual extracellular stannous ions, rendering them more readily available for oxidation by sodium hypochlorite.

Radioactive labeling of the red blood cells is completed by addition of sodium pertechnetate Tc 99m injection to the oxidized contents of the reaction vial. The sodium pertechnetate ion diffuses across the red blood cell membrane and is reduced by the intracellular stannous ion. The reduced technetium Tc 99m cannot diffuse out of the red blood cell. The red blood cell labeling is essentially complete within 20 minutes of sodium pertechnetate Tc 99m injection addition to the reaction vial. Red blood cell labeling efficiency of ≥ 95% is typically obtained using this *in vitro* labeling procedure. *In vitro* Tc 99m red blood labeling efficiency can decrease when excessive amounts of Tc 99m are allowed to accumulate in the sodium pertechnetate Tc 99m generator eluate; in this situation, efficiency decreases even further if excess (i.e.: > 0.15 mL per mL of blood) ACD buffer is used. Therefore, long Tc 99m in-growth times are to be avoided;

the use of fresh (≤ 24 hour in-growth time) sodium pertechnetate Tc 99m generator eluate is recommended. After the labeling procedure is completed, the Tc 99m Red Blood Cells are then re-injected intravenously into the patient for gamma scintigraphic imaging.

Following intravenous injection, the Technetium Tc 99m Red Blood Cells distribute within the blood pool with an estimated volume of distribution of approximately 5.6% of the body weight. The technetium Tc 99m is well retained in the blood pool with an estimated biological half-life of approximately 29 hours. Of the total technetium Tc 99m retained in the whole blood pool 24 hours after administration, 95% remains bound to the red blood cells. Approximately 25% of the injected dose of Tc 99m is excreted in the urine in the first 24 hours.

STORAGE AND STABILITY

The kit should be stored at controlled room temperature 20° to 25°C (68° to 77°F). Syringe I should be protected from light if not stored in the kit tray.

It is recommended that the labeled red blood cells be administered within 30 minutes of preparation or as soon as possible thereafter. A small study showed that Technetium Tc 99m-Labeled Red Blood Cells prepared with Ultratag™ RBC have equivalent *in vivo* labeling efficiency when administered both immediately after preparation (5 patients studied) and at 6 hours after preparation (6 patients studied) with a 24-hour labeling efficiency averaging 97% for both groups.

SPECIAL HANDLING INSTRUCTIONS

As in the use of any other radioactive material, care should be taken to minimize radiation exposure to patients consistent with proper patient management, and to minimize radiation exposure to occupational workers.

This kit may be received, used and administered only by authorized persons in designated clinical settings. Its receipt, storage, use, transfer and disposal are subject to the regulations and/or appropriate licenses of local competent official organizations.

DOSAGE FORMS, COMPOSITION AND PACKAGING

Catalogue Number – 068

Ultratag™ RBC consists of three separate non-radioactive components:

1. 10 milliliter reaction vial containing:

    - Stannous chloride, dihydrate ($SnCl_2 \bullet 2H_2O$) 50 µg minimum; 96 µg theoretical
    - Tin chloride (stannous and stannic) dihydrate, as stannous chloride ($SnCl_2 \bullet 2H_2O$) - 105 µg maximum
    - Sodium citrate, dihydrate - 3.67 mg
    - Dextrose, anhydrous - 5.50 mg

Prior to lyophilization, the pH is adjusted to 7.1 - 7.2 with sodium hydroxide. The contents of the vial are lyophilized and stored under argon.

2. Syringe I contains:

    - Sodium hypochlorite - 0.6 mg in sterile water for injection

The total volume of this syringe is 0.6 mL. Sodium hydroxide may have been added for pH adjustment. The pH of this solution is 11 - 13.

3. Syringe II contains:

    - Citric acid, monohydrate - 8.7 mg
    - Sodium citrate, dihydrate - 32.5 mg
    - Dextrose, anhydrous - 12.0 mg in sterile water for injection

The total volume of this syringe is 1.0 mL. The pH range of this solution is adjusted to 4.5 - 5.5 with sodium citrate or citric acid.

PART II: SCIENTIFIC INFORMATION

PHARMACEUTICAL INFORMATION

Drug Substance

Proper name:	Kit for the Preparation of Technetium Tc 99m-Labeled Red Blood Cells
Chemical name:	Not applicable
Molecular formula and molecular mass:	Not applicable
Structural formula:	Not applicable
Physicochemical properties:	Technetium Tc 99m decays by isomeric transition with a physical half-life of 6.02 hours.

Product 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 is listed in the table below.

Principal Radiation Emission Data

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

External Radiation

The specific gamma ray constant for technetium Tc 99m is 0.78 R/mCi-hr at 1 cm. The first half-value thickness of lead (Pb) for Technetium Tc 99m is 0.017 cm. A range of values for the relative attenuation of the radiation emitted by radionuclide resulting from the interposition of various thicknesses of lead (Pb) is presented in the following table. For example, the use of 0.25 cm of lead will decrease the external radiation exposure by a factor of about 1000.

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 presented in table below.

Physical Decay Chart: Technetium Tc 99m, Half-Life 6.02 hours

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

* Calibration time

CLINICAL TRIALS

No data available.

DETAILED PHARMACOLOGY

See ACTION AND CLINICAL PHARMACOLOGY in PART I of the Product Monograph.

TOXICOLOGY

The only kit-related change to cell morphology seems to be an increased degree and incidence of crenation (which is mostly reversible). Acute toxicological studies in rats and beagle dogs revealed no grossly visible morphologic abnormalities that were considered treatment-related. A 14-day sub-acute toxicological study in dogs revealed no treatment-related effects on mortality, body weight, food consumption, hematology, clinical chemistry, urinalysis and organ/body weight ratios. Post-mortem examinations of these dogs, both gross and microscopic, did not reveal any changes that could be unequivocally attributed to an effect of the Ultratag™ RBC kit.

Bio-distribution studies in rats showed accumulation of the labeled red blood cells within the blood pool five minutes post-injection. The primary route of excretion in

rodents is the urine, with 50 % of the dose being eliminated within 24 hours, and fecal excretion being 7 % over this time period.

As with other radiopharmaceuticals which distribute intracellularly, there may be increased risk of chromosome damage from Auger electrons if nuclear uptake occurs.

REFERENCES

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

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3. Russell JR, Stabin MG, Sparks RB and Watson EE. Radiation Absorbed Dose to the Embryo/Fetus from Radiopharmaceuticals, Health Physics. 73(5):756-769, 1997.

4. Srivastava Syresh and Chervu L. Rao. Radionuclide - Labeled Red Blood Cell, Seminars in Nuclear Medicine. 1984:14, 68-82.

PART III: CONSUMER INFORMATION
Ultratag™ RBC
Kit for the Preparation of Technetium Tc 99m-Labeled
Red Blood Cells

This leaflet is part III of a three-part "Product Monograph" published when Ultratag™ RBC was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about Ultratag™ RBC. Contact your doctor if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:
Ultratag™ RBC is an imaging agent that is used primarily in cardiac function studies. Ultratag™ RBC is also used in detecting sites of gastrointestinal bleeding.

What it does:
Ultratag™ RBC kit connects the radioactivity to the patient's red blood cells.

Once the medicine is injected, your doctor will take an image (scan) of your heart or gastrointestinal tract. The areas where the radioactivity collects will appear in the image and help your doctor make the diagnosis.

What the medicinal ingredient prepared using this kit is:
Technetium Tc 99m Red Blood Cells.

What the important non-medicinal ingredients are:
Citric acid monohydrate, dextrose anhydrous, sodium citrate dihydrate, sodium hypochlorite, tin chloride (stannous and stannic) dihydrate.

For a full listing of non-medicinal ingredients see Part 1 of the product monograph.

WARNINGS AND PRECAUTIONS

Since Ultratag™ RBC is a radiopharmaceutical, it can only be given by a healthcare professional who is specially trained and experienced 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.

Procedures involving the withdrawal and re-injection of blood can cause infection. Proper procedures are used to reduce the risk of infection.

The radiolabeled red blood cells must be re-injected only into the patient from whom the blood was drawn.

BEFORE you receive Ultratag™ RBC talk to your doctor if:

- You had any allergic reaction to this radiopharmaceutical in the past or its ingredients.
- There is a possibility that you may be pregnant. If there is a need to consider Ultratag™ RBC during your pregnancy, your doctor will discuss the benefits and risks of giving it to you.
- You are breastfeeding your baby. Technetium Tc 99m is excreted in human milk during lactation; therefore, formula feedings should be substituted for breastfeeding for at least four hours after administration of Tc 99m labeled red blood cells.

Ultratag™ RBC is recommended for patients 18 years of age and older. If your doctor believes it is necessary to give Ultratag™ RBC to a patient under 18, he or she will discuss the benefits and risks with you.

Safety precautions to be followed for up to 12 hours after receiving Ultratag™ RBC:
- Men should use toilet instead of urinal.
- Toilet should be flushed several times after use.
- Wash hands thoroughly after using toilet.

If the patient has difficulties with bladder control, special precautions should be used to minimize the risk of radioactive contamination of clothing, bed linen and the patient's environment.

INTERACTIONS WITH THIS MEDICATION

No interactions are known, however, your doctor should be informed about all the prescribed or over-the-counter products you use.

PROPER USE OF THIS MEDICATION

This product Ultratag™ RBC will be administered under the supervision of a physician who is trained and experienced in the safe use of radiopharmaceuticals.

Your blood sample is collected (1 to 3 mL) using heparin or ACD to prevent your blood from clotting. This blood is then transferred to the reaction vial and gently mixed to dissolve the material then allowed to react for 5 minutes. The prepared blood is then re-injected into your vein.

The prepared blood should be used within 30 minutes of preparation.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

No side effects are known. Should you experience any side effect following the administration of Ultratag™ RBC, be sure to tell your doctor.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- **Report online at www.healthcanada.gc.ca/medeffect**
- **Call (toll-free) at 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
  - **Fax (toll-free) to 1-866-678-6789, or**
  - **Mail to: Canada Vigilance Program**
    Health Canada
    Postal Locator 1908C
    Ottawa, ON, K1A 0K9

You can also report suspected adverse reactions directly to Curium Canada Inc. by one of the following 2 ways:

- **Call (toll-free) to 1-866-789-2211**
- **Mail to: Curium Canada Inc.**
  c/o Pharmacovigilance Department
  2572 Boul. Daniel-Johnson, Suite 248
  Laval, QC, H7T-2R3

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be obtained by contacting the sponsor, Curium Canada Inc. at 1-866-885-5988.

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