Product Monograph

Including Patient Medication Information

Drax Exametazime®

(Kit for the Preparation of Technetium Tc 99m Exametazime for Leukocyte Labelling)

Powder for Solution, for intravenous injection, 0.5 mg exametazime (185 to 370 MBq (5 to 10 mCi) Technetium Tc 99m after reconstitution) per vial

Diagnostic Radiopharmaceutical Kit

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Certain sections or subsections that are not applicable at the time of the preparation of the most recent authorized product monograph are not listed

Part 1: Healthcare Professional Information

1. Indications

Drax Exametaxime® (Kit for the Preparation of Technetium Tc 99m Exametazime for Leukocyte Labelling) is indicated for:

- The detection of sites of focal infection, especially abdominal abscess.
- As an adjunct in the investigation of pyrexia of unknown origin (PUO).
- The evaluation of inflammatory conditions not associated with infection such as inflammatory bowel disease (IBD).

1.1. Pediatrics

Pediatrics (< 18 years of age): No data are available to Health Canada; therefore, Health Canada has not authorized an indication for pediatric use.

1.2. Geriatrics

Geriatrics (> 65 years of age): No data are available to Health Canada; therefore, Health Canada has not authorized an indication for geriatric use.

2. Contraindications

Drax Exametazime® (Kit for the Preparation of Technetium Tc 99m Exametazime for Leukocyte Labelling) is contraindicated in patients who are hypersensitive to this drug or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container. For a complete listing, see 6 Dosage Forms, Strengths, Composition, and Packaging.

3. Serious Warnings and Precautions Box

Technetium (^{99m}Tc) Exametazime Injection should be used only by those health professionals who are appropriately qualified in the use of radioactive prescribed substances in or on humans.

4. Dosage and Administration

4.1. Dosing Considerations

Using proper shielding, parenteral drug products should be inspected for particulate matter and discoloration prior to administration. Do not use if the solution contains particulate matter or is not a clear solution. Measure patient dose with a suitable radioactivity calibration system immediately prior to administration.

4.2. Recommended Dose and Dosage Adjustment

Recommended dosage of Drax Exametazime® for adults (70 kg), the usual administered activity is 185 to 370 MBq (5 to 10 mCi) of Tc 99m labelled leukocytes. Administer the Tc 99m labelled leukocyte suspension using a 19G needle as soon as possible after labelling.

4.3. Reconstitution

Parenteral Products:

Reconstitute Tc 99m Exametazime with generator eluate (See Preparation of Tc 99m Exametazime). Use only eluate from a Tc 99m generator which was eluted within the previous 24 hours. Measure the radioactivity and record as item on the Labelling Efficiency Worksheet. Use for radiolabelling white blood cell (WBC) within 30 minutes. See 4.7 Instructions for Preparation and Use and 11 Storage, Stability and Disposal.

Table 1 – Reconstitution

Vial Size	Volume of Diluent To Be Added to Vial	Approximate Available Volume	Concentration Per mL
10 mL	5 mL	5 mL	74 to 370 MBq/mL (2 to 10 mCi/mL)

4.4. Administration

See 4.7 Instructions for Preparation and Use.

- Use strict aseptic procedures throughout preparation and handling.
- Visually inspect the reconstituted Tc 99m exametazime solution for particulate matter and discoloration prior to radiolabelling of white blood cells. Do not use the reconstituted solution if there is evidence of particulate matter or discoloration.
- Follow the directions of drug preparation carefully to ensure efficient leukocyte labelling.
- Measure patient dose with a suitable radioactivity calibration system immediately prior to administration.

4.6. Image Acquisition and Interpretation

Dynamic imaging may be performed for the first 60 minutes after injection to assess lung clearance and to visualize immediate cell migration.

Static imaging at 0.5 to 1.5 hours, 2 to 4 hours and if necessary, at 18 to 24 hours post injection should be performed to detect focal accumulation of activity. Care should be taken to distinguish between leukocyte localization and normal biodistribution.

4.7. Instructions for Preparation and Use of Radiopharmaceuticals

Preparation of Autologous Leukocytes

IMPORTANT - Label all syringes and tubes used in this labelling procedure with the patient's name and unique identification number.

Leukocyte Harvest and Separation

1. Draw 2 mL of Heparin and 8 mL of 6% Hydroxyethyl starch into a 60 mL plastic syringe.

2. Withdraw approximately 40 mL whole blood from the patient into the syringe using a 19-gauge Butterfly needle infusion set. Close the syringe with a sterile hub.

3. Gently mix the contents for 2 minutes.

4. Clamp the syringe barrel to the ring stand in an upright (hub side up) position and tilt the syringe approximately 10 to 20 degrees from its position perpendicular to the bench.

5. Allow the syringe to stand a minimum of 60 minutes until the red blood cells sediment and the supernatant looks clear.

6. Using an infusion set, transfer the leukocyte-rich plasma (LRP), the supernatant, from the previous step, into a sterile, conical centrifuge tube marked "WBC" (white blood cell) and assure that only a minimum amount of red cells enter the centrifuge tube.

7. Immediately centrifuge the capped WBC tube at 400 g to 450 g for 5 minutes. The plasma will separate out into a liquid [leukocyte poor plasma (LPP)] and a solid (WBC button). The WBC button often contains a small number of red blood cells and may appear red.

8. Transfer the leukocyte poor plasma (LPP) into another sterile centrifuge tube marked as "Plasma" tube, without disturbing the WBC button. Save the LPP in the Plasma tube for later use (Steps 16 and 19).

Red Blood Cell Lysis and Washing

9. Add 1 mL Sodium Chloride (NaCl) Injection, USP (0.9%) to the WBC button and suspend.

10. Add the following to the WBC suspension in succession and swirl the centrifuge tube (WBC tube) for 5 to 30 seconds after each addition:

    a) 9 mL sterile water;
    b) 2 mL of 5% NaCl; and

c) 10 mL of 0.9% NaCl.

Note: Attention to timing is important as exposing leukocytes to a hypotonic solution for a prolonged period will damage leukocytes and result in poor leukocyte labelling results.

11. Cap the WBC tube and centrifuge at 400 g for 5 to 7 minutes. Draw off the supernatant into the "Waste" tube.

12. Add 1.5 mL of 0.9% Na Cl and re-suspend the WBC button by gentle shaking.

13. Reconstitute Tc 99m exametazime with generator eluate (See Preparation of Tc 99m Exametazime). Measure the radioactivity and record as item (1) on the Labelling Efficiency Worksheet. Use for radiolabelling WBC within 30 minutes.

Labelling of Autologous Leukocytes with Tc 99m Exametazime

14. Carefully add the reconstituted Tc 99m exametazime to the WBC tube containing the WBC button isolated in Step 12.

15. Incubate the WBCs at room temperature for 15 minutes. Swirl during the incubation every 5 minutes.

16. Add 5 mL of LPP (from Step 8) to the WBC tube. Cap the WBC tube and centrifuge at 400 g for 5 minutes.

17. Carefully remove the supernatant and place into the tube labelled “Wash.” Keep the labelled white cells in the WBC tube.

18. Measure the radioactivity of the Wash tube and record as item (2) on the Labelling Efficiency Worksheet.

19. Add 5 to 10 mL of LPP (from Step 8) to the Tc 99m labelled leukocyte preparation (WBC tube). Gently swirl to mix.

20. Draw up the labelled cells into a non-heparinized syringe with a large bore needle (no smaller than 19-gauge) and cap it with a sterile hub. Measure the radioactivity of the cells and record as item (3) on the Labelling Efficiency Worksheet.

21. Verify the identity of the leukocyte recipient.

22. Labelled cells are now ready for administration. Administer as soon as possible and preferably within 1 to 2 hours after labelling.

23. Calculate the labelling efficiency from the Labelling Efficiency Worksheet:

$$\frac{\text{Radioactivity of the cells [item (3)]}}{\text{Radioactivity of the cells [item(3)]} + \text{activity in the supernatant [item (2)]}}$$

A labelling efficiency of about 55% might be expected.

Preparation of Tc 99m Exametazime

The Tc 99m labelling reaction involved in preparing the agent depends on maintaining the stannous ion in the reduced state. Any oxidant present in the sodium pertechnetate Tc 99m may adversely affect the radiolabelling efficiency.

- Elute the Tc 99m generator according to the manufacturer's instructions.
- Use only eluate from a Tc 99m generator which was eluted within the previous 24 hours.
- Prepare the Tc 99m exametazime with eluate that is not more than 2 hours old.
- Before reconstitution, add up to 5 mL preservative-free, non-bacteriostatic Sodium Chloride Injection USP (0.9%) to the generator eluate to achieve a radioactive concentration no greater than 74 to 370 MBq/mL (2 to 10 mCi/mL).
- Add 370 MBq up to 2000 MBq – recommended 1110 MBq (10 mCi up to 54 mCi – recommended 30 mCi) of sodium pertechnetate Tc 99m to Drax Exametazime® vial.
- Measure the radioactivity and record as item (1) on the Labelling Efficiency Worksheet.
- Use a sample for Quality Control.
- Maintain reconstituted product at 20°C to 25°C.
- Use for WBC labelling within 30 minutes following reconstitution.
- Discard any unused material according to local radiation safety procedures.

Radiochemical Purity Measurement - Quality Control of Tc 99m Exametazime

- Obtain the Following Materials:

  SG ITLC strips 6 cm x 0.7 cm

  Whatman Grade 31ET chromatographic paper strip 6 cm x 0.7 cm

  MEK (methyl ethyl ketone [butanone]) (HPLC Grade)

  0.9% aqueous sodium chloride (non-bacteriostatic)

  50% aqueous acetonitrile (HPLC Grade)

  Glass test tubes (12 x 75 mm) with covers

  1 mL syringes with 25-gauge needles

  Collimated radiation detector

- Perform radiochemical purity testing of Tc 99m exametazime before leukocyte labelling and within 2 minutes of reconstitution.
- This entire radiochemical purity testing procedure takes approximately 15 minutes.

- A combination of 3 chromatographic systems is necessary for the complete definition of the radiochemical composition of the injection.
    - **System 1:** methyl ethyl ketone (MEK) + SG ITLC strip
    - **System 2:** 0.9% non-bacteriostatic sodium chloride solution + SG ITLC strip
    - **System 3:** 50% acetonitrile solution + Whatman 31ET paper strip
- Three potential radiochemical impurities may be present in the prepared injection of the lipophilic Tc 99m exametazime complex:
    - Secondary Tc 99m exametazime complex
    - Free Tc 99m pertechnetate
    - Reduced-hydrolyzed Tc 99m

Method

1. Prepare three chromatographic systems using 12 mm × 75 mm chromatographic tubes with the following solvents (identify the solvent in each tube):
   System 1: 0.3 mL of fresh methyl ethyl ketone (MEK)
   System 2: 0.9% non-bacteriostatic sodium chloride solution
   System 3: 50% acetonitrile solution, prepared with non-bacteriostatic water
2. Apply 5 mcL of freshly prepared Tc 99m exametazime solution (within 2 minutes of reconstitution) about 1 cm from the bottom of three strips: two 6 cm × 0.7 cm instant thin-layer chromatographic strips and one 6 cm × 0.7 cm strip of chromatographic paper. Do not allow to dry**.**
3. Place one SG ITLC strip into the MEK tube (**System 1**), the second SG ITLC strip into the saline tube (**System 2**) and the Whatman 31ET paper strip into the 50% acetonitrile tube (**System 3**). Make sure strips are not adhering to the sides of the tube.
4. Allow the chromatograms to develop until the solvent front has moved to the top of the strips. Remove the strips from the tubes, and allow the solvents to evaporate.
5. Determine the radioactive distribution by scanning the strip sections, using a suitable collimated radiation detector.

Interpretation of Chromatograms

6. Using the Radiochemical Purity Worksheet, record the following counts:

System 1 (SG ITLC: MEK [butanone])

Migrate at R_f 0.8 to 1	Lipophilic Tc 99m exametazime complex and Tc 99m pertechnetate
Origin	Secondary Tc 99m exametazime complex and reduced-hydrolyzed Tc 99m

System 2 (SG ITLC: 0.9% sodium chloride)

Migrate at R_f 0.8 to 1	Tc 99m pertechnetate
Origin	Lipophilic Tc 99m exametazime complex, secondary Tc 99m exametazime complex and reduced-hydrolyzed Tc 99m

System 3 (Whatman 31ET: 50% aqueous acetonitrile)

Migrate at R_f 0.8 to 1	Lipophilic Tc 99m exametazime complex, secondary Tc 99m exametazime complex and Tc 99m pertechnetate
Origin	Reduced-hydrolyzed Tc 99m

7. Determine and record on the Radiochemical Purity Worksheet:

   % at the origin of saline strip (D)

   % at the origin of MEK strip (B)

   % at the solvent front of saline strip (C) [% Tc 99m pertechnetate]

   % at the origin of Whatman 31ET paper strip (F) [% reduced-hydrolyzed Tc 99m]

8. Calculate the radiochemical purity:

   % lipophilic exametazime complex = % at the origin of saline strip (D) – % at the origin of MEK strip (B)

9. Do not use if radiochemical purity of Lipophilic Tc 99m Exametazime is less than 80%.

4.8. Radiation Dosimetry

The effective dose resulting from the administration of a (maximal recommended) activity of 370 MBq for an adult weighing 70 kg is about 4.1 mSv.

The estimated absorbed radiation doses to various organs following the intravenous administration of Tc99m labeled leukocytes given by International Commission on Radiological Protection (ICRP) Publication 128 are provided in Table 2:

Table 2 – Estimated Absorbed Radiation Dose for in vivo localization of Tc 99m labelled leukocytes

Organ	Absorbed dose per unit radioactivity (mGy/MBq)	Calculated absorbed dose for 370 MBq administered (mGy)
Adrenals	0.012	4.440
Bone surfaces	0.016	5.920
Brain	0.002	0.851
Breast	0.002	0.888
Gallbladder wall	0.008	3.110
Gastrointestinal tract:		
- Stomach wall	0.008	3.000
- Small intestine wall	0.005	1.700
- Colon wall	0.004	1.590
- (Upper large intestine wall)	0.005	1.740
- (Lower large intestine wall)	0.004	1.370
Heart wall	0.009	3.480
Kidneys	0.012	4.440
Liver	0.020	7.400
Lungs	0.008	2.890
Muscles	0.003	1.220
Oesophagus	0.004	1.300
Ovaries	0.004	1.440
Pancreas	0.013	4.810
Red marrow	0.023	8.510
Skin	0.002	0.666
Spleen	0.150	55.500
Testes	0.002	0.592
Thymus	0.004	1.300
Thyroid	0.003	1.070
Urinary bladder wall	0.003	0.962
Uterus	0.003	1.260
Remaining organs	0.003	1.260
Effective dose	0.011 mSv/MBq	4.070 mSv

5. Overdose

In the event of the administration of a radiation overdose, hydration and frequent urination should be encouraged to minimize the absorbed dose to patient.

For the most recent information in the management of a suspected drug overdose, contact your regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669)

6. Dosage Forms, Strengths, Composition, and Packaging

Table 3 – Dosage Forms, Strengths, Composition and Packaging

Route of Administration	Dosage Form/Strength/Composition	Non-medicinal Ingredients
Intravenous	Powder for solution, 0.5 mg exametazime per 10 mL vial 185 to 370 MBq (5 to 10 mCi) per 10 mL vial after reconstitution	Sodium chloride Stannous chloride dihydrate

Each Drax Exametazime® kit is supplied as one package containing: 5 single-use vials (0.5 mg/vial). Each vial contains a non-radioactive sterile, non-pyrogenic lyophilized mixture of: 0.5 mg of exametazime, 0.0076 mg stannous chloride dihydrate, 0.0006 mg stannous tin minimum; 0.004 mg total stannous and stannic tin maximum, and 4.5 mg sodium chloride; 10 Radioassay information labels with radiation warning symbol; 10 Patient identification labels; 5 Sheets of Labelling Efficiency/Radiochemical Purity Testing Worksheets; 1 Leukocyte Labelling Schematic; 1 Package Insert.

Sodium Pertechnetate Tc 99m is not part of Drax Exametazime® kit. Before reconstitution and radiolabelling with Tc 99m, the contents of the kit are not radioactive.

6.1. Physical Characteristics

Technetium 99m decays by isomeric transition with a physical half-life of 6.02 hours.

Photons that are useful for detection and imaging studies are listed in Table 4.

Table 4 – Principal Radiation Emission Data

Radiation	Mean %/ Disintegration	Mean Energy (keV)
Gamma-2	87.87	140.50

6.2. External Radiation

The specific gamma ray constant for Tc 99m is 206 mcCkg^{-1}/37MBq-hr.(0.78R/millicurie-hr.) at 1 cm. The first half-value layer is 0.02 cm of 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 5. For example, the use of a 0.25 cm thickness of Pb will attenuate the radiation emitted by a factor of about 1000.

Table 5. Radiation Attenuation by Lead Shielding

Shield Thickness (Pb) cm	Coefficient of Attenuation
0.02	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 of radioactivity that remain at selected intervals after time of calibration are shown in Table 6.

Table 6. Physical Decay Chart: Technetium 99m, Half-Life 6.02 Hours

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

*Calibration time

7. Warnings and Precautions

See 3 Serious Warnings and Precautions Box.

The product should be administered under the supervision of a healthcare professional 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 radiopharmaceutical product 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.

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.

The contents of the kit are not radioactive. However, after the sodium pertechnetate Tc 99m is added, adequate shielding of the final preparation must be maintained to minimize radiation exposure to occupational workers and patients.

The contents of the Drax Exametazime® kit are intended for use in the preparation of Tc 99m exametazime injection and are NOT to be directly administered to the patient.

General

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

Sodium Chloride Injection, USP (0.9%) must be used as the diluent. Do not use bacteriostatic sodium chloride as a diluent for sodium pertechnetate Tc 99m injection because it will increase the oxidation products and adversely affect the biological distribution of Tc 99m exametazime injection.

Radiopharmaceuticals should be used only by those medical practitioners who are appropriately qualified in the use of radioactive prescribed substances in or on humans.

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.

The content of the vials is sterile and non pyrogenic. It is essential that the user follows directions carefully and adheres to strict aseptic technique.

It should also be noted that materials used in cell separation may cause hypersensitivity reactions. It is essential that cells are washed free of sedimentation agents before they are reinjected into the patient.

Carcinogenesis and Genotoxicity:

See 16 Non-Clinical Toxicology.

Contamination:

Care should be taken when handling blood specimens to be labelled using this radiopharmaceutical. Even if the subject has been tested, no method can offer complete assurance that Hepatitis B Virus, Human Immunodeficiency Virus (HIV) or other infectious agents are absent. All human blood samples should be considered potentially infectious. Precautions for handling are as those for handling radioactive materials.

Immune:

The possibility of hypersensitivity including serious signs and symptoms of anaphylaxis should always be considered. Advanced life support facilities should be readily available.

Reproductive Health:

- **Fertility**

Since adequate reproduction studies have not been performed in animals to determine whether this drug affects fertility in males and females, has teratogenic potential, or has other adverse effects on the fetus, this radiopharmaceutical preparation should not be administered to pregnant or nursing women unless it is considered that the benefits to be gained outweigh the potential hazards. See 7.1.1 Pregnancy.

7.1. Special Populations

7.1.1. Pregnancy

In women of childbearing potential, examinations using radiopharmaceuticals should ideally be performed during the first ten days following the onset of menses, or after ensuring the woman is not pregnant. The benefit of using a diagnostic radiopharmaceutical should be weighed against the possible risk to an embryo or a fetus.

7.1.2. Breastfeeding

Nursing mothers who are using radiopharmaceuticals should switch their child to formula for the duration of treatment and until their healthcare professional advises them that it is safe to reintroduce breastfeeding.

7.1.3. Pediatrics

Pediatrics (< 18 years of age): No data are available to Health Canada; therefore, Health Canada has not authorized an indication for pediatric use.

7.1.4. Geriatrics

Geriatrics (> 65 years of age): No data are available to Health Canada; therefore, Health Canada has not authorized an indication for geriatric use.

8. Adverse Reactions

8.1. Adverse Reaction Overview

Reports of hypersensitivity reactions, possibly anaphylactic in nature, following administration of Tc 99m labelled leukocytes prepared using Tc 99m exametazime have been received which are listed below. See 8.5. Post-Market Adverse Reactions.

8.5. Post-Market Adverse Reactions

Immune system disorders	Hypersensitivity (including rash, erythema, urticaria, angioedema, pruritus), anaphylactoid reaction or anaphylactoid shock.
Nervous system disorders	Headache, dizziness, paraesthesia

Vascular disorders	Flushing
Gastrointestinal disorders	Nausea, Vomiting
General disorders and administration site conditions	Asthenic conditions (e.g. malaise, fatigue)

In case of side effects following administration of radiopharmaceuticals, users should ensure the availability of appropriate medical treatment at the time of administration of any radiopharmaceutical to the patient.

9. Drug Interactions

9.3. Drug Behavioral Interactions

The interaction of Tc 99m exametazime injection with individual behavioural risks (e.g. cigarette smoking, cannabis use, and/or alcohol consumption) has not been studied.

9.4. Drug-Drug Interactions

Interactions with other drugs have not been established.

9.5. Drug-Food Interactions

Interactions with food have not been established.

9.6. Drug-Herb Interactions

Interactions with herbal products have not been established.

9.7. Drug-Laboratory Test Interactions

Interactions with laboratory tests have not been established.

10. Clinical Pharmacology

10.1. Mechanism of Action

The small, lipophilic nature of the Tc-99m Exametazime complex facilitates its uptake by leukocytes, after which Tc-99m is selectively retained within neutrophils. The superior imaging characteristics of Tc 99m have led to a search for a suitable method to label leukocytes with this nuclide. Labelling by means of complexes such as Tc 99m oxine, Tc 99m pyrophosphate and medronate and the incorporation of Tc 99m colloids by phagocytes have been proposed, but all suffer deficiencies either in label stability or in “activation” or damage to leukocytes during the labelling procedure, leading to an unnatural biodistribution on reinjection.

10.2. Pharmacodynamics

Leukocytes are involved in a number of the body’s responses to disease including infection, inflammation and infarction. Techniques have been developed to tag leukocytes with a radiolabel using In 111, in order to subsequently assess sites of localization and consequently pathology using a gamma camera. In 111

labelled leukocytes are an established non-invasive means of diagnosing a variety of inflammatory conditions in which granulocyte migration is a prominent feature.

10.3. Pharmacokinetics

The small lipophilic nature of the Tc 99m exametazime complex facilitates its uptake into leukocytes, following which the Tc 99m is selectively retained in neutrophils. Provided the recommended cell separation and labelling procedures are carried out, the Tc 99m labelled leukocytes do not appear to suffer significant damage or "activation", as evidenced by their *in vivo* recovery and lack of lung and liver uptake. Label elution rate is up to 10% in the first hour, declining thereafter.

Following cell separation and radiolabelling, according to the package insert instructions for CERETEC® (Kit for the Preparation of Technetium Tc 99m Exametazime Injection), a labelling efficiency of around 55% may be expected with around 78% of the label associated with the neutrophil population. Studies of elution rates indicate that Tc 99m exametazime shows relative selectivity for granulocytes and acts as an effective radiolabelling agent. Following reinjection of the Tc 99m labelled leukocytes the functional integrity of the granulocytes appears to be well maintained as the recovery of radiolabelled granulocytes (i.e., the circulatory granulocyte associated activity as a percentage of injected granulocyte associated activity) at 40 minutes after injection gave a mean value of 37% which compares favorably with pure granulocytes labelled with In 111 tropolonate. The initial biodistribution is similar to that of In 111 tropolonate labelled pure granulocytes. During the first hour following injection of Tc 99m labelled leukocytes, activity is seen in the lungs, liver, spleen, blood pool and bone marrow as well as in the bladder. The kidneys (parenchyma and/or renal pelvis) and gallbladder may also be visualized. This pattern of activity continues to be seen at 4 hours post-injection except that lung activity is greatly reduced and faint bowel activity may be visible. At 24 hours post-injection substantial colonic activity is seen, in addition to the normal areas visualized in earlier scans.

11. Storage, Stability, and Disposal

Before reconstitution, store the kit at room temperature (15°C to 30°C). After reconstitution, store the reconstituted product at 20°C to 25°C using appropriate radiation shielding.

Kit before reconstitution is stable for 12 months when stored at room temperature (15°C to 30°C).

Do not use the kit beyond the expiration date stamped on the box. After reconstitution, the Tc 99m exametazime injection should be used, within 30 minutes for leukocyte radiolabelling. Protect from freezing.

12. 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.

Part 2 : Scientific Information

13. Pharmaceutical Information

Drug Substance

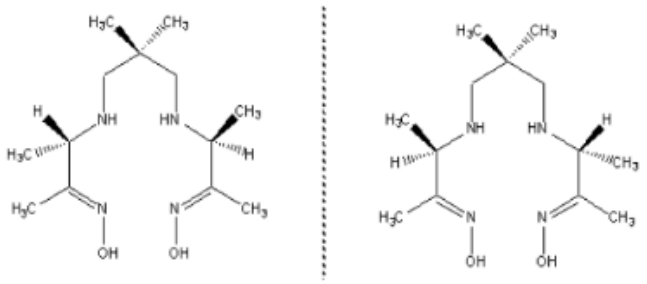
Non-proprietary name of the drug substance(s): Exametazime

Chemical name: (RR,SS)-4,8-diaza-3,6,6,9-tetramethylundecane-2,10-dione bisoxime

Molecular formula: $C_{13}H_{28}N_4O_2$;

Molecular mass: 272.39 g/mol

Structural formula:



Physicochemical properties: Solid crystalline white powder.

Product Characteristics:

Drax Exametazime® is a kit containing five (5) single-use vials. Each 10 mL, clear glass vial contains a sterile, non-pyrogenic lyophilized mixture of 0.5 mg exametazime (d,l-HMPAO), 4.5 mg sodium chloride, and 0.0076 mg stannous chloride dihydrate (minimum stannous tin 0.0006 mg; maximum total stannous and stannic tin 0.004 mg per vial), sealed under nitrogen atmosphere with a rubber closure. The product contains no antimicrobial preservative.

15. Microbiology

No microbiological information is required for this drug product.

16. Non-Clinical Toxicology

General toxicology: Toxicity studies have been performed on intravenously administered technetium 99m exametazime injection in male and female rats and rabbits. No adverse reactions or mortalities were observed at a dose level equivalent to the single injection of 1200 times the maximum human equivalent dose (MHD). Similarly, 14-day repeat-dose studies in rats and rabbits at a cumulative dose of up to 14,000 times the maximum human equivalent dose resulted in no adverse reactions or mortalities. At termination, thorough histopathology, hematology and blood chemistry revealed no abnormalities.

Carcinogenicity: No long-term animal studies have been performed to evaluate the carcinogenic

potential of Tc 99m exametazime injection.

Genotoxicity: No studies have been performed to evaluate the genotoxic potential of Tc 99m exametazime injection. As with other radiopharmaceuticals that distribute intracellularly, there may be increased risk of chromosome damage from Auger electrons if nuclear uptake occurs.

Fertility toxicology: No dedicated animal fertility studies have been performed for Tc 99m exametazime injection.

17. Supporting Product Monographs

Ceretec™ Kit for the preparation of technetium-99m exametazime injection; date of initial approval: October 21, 1986; Control no.: 216123; GE Healthcare Canada Inc.

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Drax Exametazime®
Kit for the Preparation of Technetium Tc 99m Exametazime for Leukocyte Labelling

This patient medication information is written for the person who will be taking Drax Exametazime®. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This patient medication information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about Drax Exametazime®, talk to a healthcare professional.

Serious warnings and precautions box
Drax Exametazime should be used only by those healthcare professionals who are appropriately qualified in the use of radioactive prescribed substances in or on humans.

What Drax Exametazime® is used for?

Drax Exametazime® is used:

- In the detection of sites of focal infection, especially abdominal abscess
- As an adjunct in the investigation of pyrexia of unknown origin (PUO)
- In the evaluation of inflammatory conditions not associated with infection such as inflammatory bowel disease (IBD)

How Drax Exametazime® works?

Labelled leukocytes act as an established non-invasive means of diagnosing a variety of inflammatory conditions in which granulocyte migration is a prominent feature with the help of static imaging at respective time interval post administration.

The ingredients in Drax Exametazime® are:

Medicinal ingredients: Exametazime

Non-medicinal ingredients: Sodium chloride; Stannous chloride dihydrate

Drax Exametazime® comes in the following dosage form:

Powder for solution, 0.5 mg exametazime per vial.

Do not use Drax Exametazime® if:

You are allergic (hypersensitive) to any of the Drax Exametazime ingredients as mentioned above.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Drax Exametazime®. Talk about any health conditions or problems you may have, including if:

- There is a possibility that you may be pregnant;
- You are breastfeeding;
- You had an allergic reaction to this drug or you had an imaging study with this drug before.

Other warnings you should know about:

Drink plenty of fluids and go to the toilet as much as possible for up to 24 hours after receiving the product, to help reduce radiation exposure.

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;
- If blood or urine gets onto clothing, such clothing should be washed separately or stored for 1 to 2 weeks to allow for decay and then wash

How to take Drax Exametazime®:

Drax Exametazime® will be given to you by a healthcare professional who is experienced in the use of radiopharmaceuticals.

Usual dose:

For adults (70 kg), the usual administered activity is 185 to 370 MBq (5 to 10 mCi) of Tc 99m labelled leukocytes by intravenous injection.

Overdose:

If you think you, or a person you are caring for, have taken too much Drax Exametazime®, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms. For the most recent information in the management of a suspected drug overdose, contact your regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669.

Possible side effects from using Drax Exametazime®:

These are not all the possible side effects you may have when taking Drax Exametazime®. If you experience any side effects not listed here, tell your healthcare professional.

- Headache;
- Dizziness;
- Paraesthesia;
- Flushing;
- Nausea;
- Vomiting;
- Asthenic conditions (e.g. malaise, fatigue);
- Hypersensitivity (including rash, erythema, urticaria, angioedema, pruritus);
- Anaphylactoid reaction;
- Anaphylactoid shock.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Before reconstitution, store the kit at room temperature (15°C to 30°C).

After reconstitution, store the reconstituted product at 20°C to 25°C using appropriate radiation shielding.

Keep out of reach and sight of children.

If you want more information about Drax Exametazime®:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website; the manufacturer's website https://www.jubilantradiopharma.com or by calling 1-888-633-5343 / 514-630-7080.

This leaflet was prepared by:

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