HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use DRAXIMAGE® MAA safely and effectively. See full prescribing information for DRAXIMAGE MAA.

DRAXIMAGE MAA (kit for the preparation of technetium Tc 99m albumin aggregated) injection, for intravenous or intraperitoneal use

Initial U.S. Approval: 1987

----------INDICATIONS AND USAGE----------

DRAXIMAGE MAA, after radiolabeling with sodium pertechnetate Tc 99m, is a radioactive diagnostic agent indicated for:

- Lung scintigraphy as an adjunct in the evaluation of pulmonary perfusion in adults and pediatric patients. (1)
- Peritoneovenous shunt scintigraphy as an aid in the evaluation of its patency in adults. (1)

----------DOSAGE AND ADMINISTRATION----------

- For lung scintigraphy, the following recommended activity is administered by intravenous injection:
  - Adults: 37 MBq to 148 MBq (1 mCi to 4 mCi); 200,000 particles to 700,000 particles. (2.3)
  - Pediatric patients aged 4 weeks and older: 0.925 MBq/kg to 1.85 MBq/kg of body weight (0.025 mCi/kg to 0.05 mCi/kg); The minimum activity is 7.4 MBq (0.2 mCi). The number of particles will vary with age and body weight of the pediatric patient. (2.3)
  - Pediatric patients aged less than 4 weeks: 7.4 MBq to 18.5 MBq (0.2 mCi to 0.5 mCi); 10,000 particles to 50,000 particles. (2.3)
- For scintigraphy of peritoneovenous shunts in adults: 37 MBq to 111 MBq (1 mCi to 3 mCi); 200,000 particles to 700,000 particles by intraperitoneal injection. (2.4)
- See Full Prescribing Information for radiation safety, patient preparation, drug preparation, administration, imaging, and radiation dosimetry information. (2.1, 2.2, 2.5, 2.6, 2.7)

----------DOSAGE FORMS AND STRENGTHS----------

Kit for the preparation of Technetium Tc 99m Albumin Aggregated Injection: 2.5 mg of albumin aggregated as a lyophilized powder in a multiple-dose reaction vial. Upon radiolabeling, it provides a suspension of Technetium Tc 99m Albumin Aggregated Injection. Each vial contains 3,000,000 to 8,000,000 particles. (3)

----------CONTRAINDICATIONS----------

- Severe pulmonary hypertension. (4)
- A history of hypersensitivity reactions to albumin human. (4)

----------WARNINGS AND PRECAUTIONS----------

- Patients with Pulmonary Hypertension: Administer the lowest number of particles possible and have emergency resuscitation equipment available. (5.1)
- Hypersensitivity Reactions: Have emergency resuscitation equipment and trained personnel available. Interrupt the administration if a reaction occurs during administration. Monitor patients. (5.2)
- Risk of Temporary Impediment to Blood Flow in Patients with Right-to-Left Heart Shunts: Administer the lowest possible number of particles. (5.3)
- Radiation Risks: Ensure safe handling to minimize radiation exposure to the patient and healthcare providers. (5.4)

----------ADVERSE REACTIONS----------

The following adverse reactions have been reported: Death in patients with severe pulmonary hypertension, anaphylaxis, impairment of cardiac and circulatory functions in the form of changes in respiration, pulse, and blood pressure, chest pain, and possible syncope, urticaria, reddening of the face, sweating, nausea, and injection site reaction. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Jubilant DraxImage Inc. at 1-888-633-5343 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

----------USE IN SPECIFIC POPULATIONS----------

Lactation: Temporarily discontinue breastfeeding. A lactating woman should pump and discard breastmilk for at least 24 hours after Technetium Tc 99m Albumin Aggregated Injection administration. (8.2)

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 12/2023

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

DRAXIMAGE MAA, after radiolabeling with sodium pertechnetate Tc 99m, is indicated for:

- Lung scintigraphy as an adjunct in the evaluation of pulmonary perfusion in adults and pediatric patients.
- Peritoneovenous shunt scintigraphy as an aid in the evaluation of its patency in adult patients.

2 DOSAGE AND ADMINISTRATION

2.1 Radiation Safety – Drug Handling

After radiolabeling of DRAXIMAGE MAA, the vial contains Technetium Tc 99m Albumin Aggregated Injection. Handle Technetium Tc 99m Albumin Aggregated Injection with appropriate safety measures to minimize radiation exposure *[see Warnings and Precautions (5.4)]*. Use waterproof gloves, effective radiation shielding, and other appropriate safety measures when preparing and handling Technetium Tc 99m Albumin Aggregated Injection.

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

2.2 Patient Preparation

Instruct patients to drink a sufficient amount of water to ensure adequate hydration prior to administration of Technetium Tc 99m Albumin Aggregated Injection and to continue to drink and void frequently following administration to reduce radiation exposure *[see Warnings and Precautions (5.4)]*.

2.3 Recommended Dosage for Lung Perfusion Scintigraphy

Adult Patients

The recommended activity for lung perfusion scintigraphy in adult patients is 37 MBq to 148 MBq (1 mCi to 4 mCi) by intravenous injection.

The number of particles per single injection should be 200,000 to 700,000 with the recommended number being approximately 350,000. Depending on the activity added and volume of the final radiolabeled product, the volume of the dose may vary from 0.2 mL to 1.9 mL.

The number of particles available per dose of Technetium Tc 99m Albumin Aggregated Injection will vary depending on the physical decay of the technetium-99m that has occurred. The number of particles in any dose and volume to be administered may be calculated as follows:

$$V_a = \frac{D}{C \times F_r} \quad \text{and} \quad P = \frac{V_a}{V_{Tc}} \times N$$

Where:

V_a = Volume to be administered in mL
D = Desired activity to be administered in MBq (mCi)
C = Concentration at calibration time of Sodium Pertechnetate Tc 99m Injection to be added to the reaction vial in MBq/mL (mCi/mL)
F_r = Fraction of technetium-99m remaining after the time of calibration from Table *7 [see Description (11.3)]*

P = Number of particles in dose to be administered
V_a = Volume to be administered in mL
V_{Tc} = Volume of Sodium Pertechnetate Tc 99m Injection added to reaction vial in mL
N = Number of particles per vial. The number of particles per vial for each lot is shipped with the product.

Pediatric Patients Aged 4 Weeks and Older

The recommended activity for lung perfusion scintigraphy in pediatric patients aged 4 weeks and older by intravenous injection is based on body weight and ranges from 0.925 MBq/kg to 1.85 MBq/kg (0.025 mCi/kg to 0.05 mCi/kg). The minimum recommended activity for lung perfusion scintigraphy in this age group is 7.4 MBq (0.2 mCi).

The number of particles will vary with age and body weight of the pediatric patient. Particle numbers administered in four different age and weight categories are provided in Table 1.

Table 1. Particle Numbers Administered in Four Different Age and Weight Categories of Pediatric Patients Receiving Maximum Recommended Activity of Technetium Tc 99m Albumin Aggregated Injection for Lung Perfusion Scintigraphy

Age	15 years		10 years		5 years		1 year	
Weight (kg)	55		33.5		20.3		12.1	
Maximum recommended activity	**MBq**	**mCi**	**MBq**	**mCi**	**MBq**	**mCi**	**MBq**	**mCi**
	103.6	2.8	62.9	1.7	37	1	22.2	0.6
Range of particles administered	200,000 to 700,000		200,000 to 300,000		200,000 to 300,000		50,000 to 150,000	

Pediatric Patients Aged Less Than 4 Weeks (Neonates)

The recommended activity for lung perfusion scintigraphy in neonates by intravenous injection is 7.4 MBq to 18.5 MBq (0.2 mCi to 0.5 mCi). The number of particles in neonates for lung perfusion scintigraphy ranges from 10,000 to 50,000. Use the lowest possible number of particles for neonates.

2.4 Recommended Dosage for Peritoneovenous Shunt Scintigraphy in Adults

The recommended activity for peritoneovenous shunt scintigraphy in adult patients is 37 MBq to 111 MBq (1 mCi to 3 mCi) by intraperitoneal injection. The number of particles per single injection should be 200,000 to 700,000 with the recommended number being approximately 350,000. Depending on the activity added and volume of the final radiolabeled product, the volume of the dose may vary from 0.2 mL to 1.9 mL. For calculation of the number of particles to be administered, see Recommended Dosage for Lung Perfusion Scintigraphy in Adult Patients *[see Dosage and Administration (2.3)]*. Assure uniform mixing with peritoneal fluid.

Alternatively, administer the drug by percutaneous transtubal injection. The recommended activity for percutaneous transtubal (efferent limb) administration in adult patients is 12 MBq to 37 MBq (0.3 mCi to 1 mCi) in a volume not to exceed 0.5 mL.

2.5 Directions for Drug Preparation and Handling

Procedural Precautions

- Before radiolabeling, the contents of the kit are not radioactive. Contents of the vials are intended only for use in the preparation of Technetium Tc 99m Albumin Aggregated Injection and are NOT to be administered directly to the patient. After the Sodium Pertechnetate Tc 99m Injection is added, maintain adequate shielding of the radiolabeled product.
- Use aseptic procedures throughout and take precautions to minimize radiation exposure by use of suitable shielding.
- Wear waterproof gloves during the preparation procedure.
- Before radiolabeling a vial, inspect the vial for cracks and/or a melted plug or any other indication that the integrity of the vacuum seal has been lost.
- Use only oxidant-free Sodium Pertechnetate Tc 99m Injection to maintain the stannous ion in the reduced state.

Procedure for the Preparation of Technetium Tc 99m Albumin Aggregated Injection

1) Remove the protective cap from a reaction vial and swab the rubber septum with either an alcohol swab or a suitable bacteriostatic agent to disinfect the surface.
2) Place the vial in a suitable lead vial shield which has a fitted cap.
3) The maximum activity of Sodium Pertechnetate Tc 99m Injection to be added to a reaction vial varies with the number of particles per vial and is shown in Table 2. The number of particles per vial for each lot is shipped with the product. Calculate the amount of radioactivity per vial required to maintain the number of particles per dose within a recommended range while taking into account administered activity, radioactive decay and the number of patients *[see Dosage and Administration (2.3, 2.4)]*. Other calculations for radiolabeling are permitted provided that the patient dose remains within the recommended range.

Table 2. Maximum Activity of Sodium Pertechnetate Tc 99m Injection to be Added Based on Vial Particle Number

Particles per vial	**Maximum Activity of Sodium Pertechnetate Tc 99m Injection to be added per vial**
3 million to 4 million	3.7 GBq (100 mCi)
5 million	4.44 GBq (120 mCi)
6 million to 8 million	6.85 GBq (185 mCi)

4) Using a shielded syringe, add the calculated amount of Sodium Pertechnetate Tc 99m Injection to the reaction vial aseptically.

5) Place the lead cap on the vial shield and mix the contents of the shielded vial by repeated gentle inversion until all the material is suspended. Do not shake to avoid formation of foam. To ensure maximum tagging, allow the preparation to stand for 15 minutes after mixing.
6) Using proper shielding, visually inspect the vial to ensure that the suspension is free of foreign matter before proceeding. Do not administer if foreign particulates are found in the preparation.
7) Assay the product in a suitable dose calibrator, record the radioassay information on the label with radiation warning symbol, and attach it to the vial shield.
8) No less than 90% of the sodium pertechnetate Tc 99m added to the reaction vial is bound to albumin aggregated at the time of preparation and remain bound throughout the usage lifetime of the preparation.

Storage and Handling of Technetium Tc 99m Albumin Aggregated Injection

- Store the radiolabeled product in the lead vial shield with cap in place during its in-use shelf life. Store the radiolabeled product refrigerated at 2 ºC to 8 ºC (36 ºF to 46 ºF) when not in use and use within 12 hours from the time of radiolabeling depending on the number of particles per vial, the activity added at radiolabeling and the final dose to be administered to the patient *[see Dosage and Administration (2.3, 2.4)]*.
- Technetium Tc 99m Albumin Aggregated Injection is physically unstable and consequently the particles settle with time. Failure to agitate the vial adequately before administration may result in non-uniform distribution of radioactive particles.
- Do not use if clumping of the contents is observed.
- Since the vials are sealed under an atmosphere of nitrogen to prevent oxidation of the complex, do not vent the vials. If repeated withdrawals are made from the vial, minimize replacement of the contents with air.
- Dispose unused Technetium Tc 99m Albumin Aggregated Injection in compliance with appropriate regulations.

2.6 Administration and Imaging Instructions

- Position the patient under the imaging apparatus before administration of Technetium Tc 99m Albumin Aggregated Injection because of rapid lung clearance of technetium Tc 99m albumin aggregated.
- Using proper shielding, visually inspect for foreign particulate matter and discoloration prior to administration. Do not administer if foreign particulates are found in the preparation.
- Mix the contents of the vial by gentle inversion just prior to withdrawing a patient dose.
- Withdraw the patient dose aseptically using a sterile needle (18 gauge to 21 gauge) and a shielded syringe.
- Measure the patient dose by a suitable radioactivity calibration system immediately prior to administration.
- Mix the contents of the syringe just before injection.
- Slow injection is recommended.
- If blood is drawn into the syringe, any unnecessary delay prior to injection may lead to clot formation.
- Begin lung imaging immediately after intravenous administration of Technetium Tc 99m Albumin Aggregated Injection. Due to high kidney uptake, imaging later than one-half hour after administration is not recommended.

- For peritoneovenous shunt imaging, obtain serial images of both the shunt and target organ.

2.7 Radiation Dosimetry

Intravenous Administration

Estimated radiation absorbed doses from intravenous administration are shown in Table 3.

Table 3. Estimated Radiation Absorbed Doses From Intravenous Administration of Technetium Tc 99m Albumin Aggregated Injection for Lung Perfusion Scintigraphy

Absorbed Dose per Activity Administered (microGy/MBq)						
Organs	**Adults**	**15 years**	**10 years**	**5 years**	**1 year**	**Neonates**
Total body	4.05	3.96	7.63	8.38	13.5	32.4
Lungs	59.5	74.3	138	157	297	1027
Liver	4.86	11.6	28.6	16.8	27	75.7
Spleen	4.59	*--	--	--	--	--
Kidneys	2.97	--	--	--	--	--
Bladder Wall						
2 hour void	8.11	--	--	--	67.6	114
4.8 hour void	14.9	--	62	83.8	--	--
No voiding intervals	--	39.6	--	--	--	--
Testes						
2 hour void	1.62	--	--	--	--	--
4.8 hour void	1.76	--	--	--	--	--
No voiding intervals	--	3.47	3.18	5.14	5.86	16.8
Ovaries						
2 hour void	2.03	--	--	--	--	--
4.8 hour void	2.3	--	--	--	--	--
No voiding intervals	--	3.96	7	5.14	9.01	20.5

*--: Not available

Intraperitoneal Administration

Estimated radiation absorbed doses from intraperitoneal administration are shown in Table 4.

Table 4. Estimated Radiation Absorbed Doses From Intraperitoneal Administration of Technetium Tc 99m Albumin Aggregated Injection for Peritoneovenous Shunt Scintigraphy in Adults

Absorbed Dose per Activity Administered (microGy/MBq)		
Organs	**Shunt Patency (Open)**	**Shunt Patency (Closed)**
Lung	62.2	15.1
Ovaries or Testes	1.62 to 2.7	15.1
Organ in the Peritoneal Cavity	*--	15.1
Total Body	3.24	5.14

*--: Not available

3 DOSAGE FORMS AND STRENGTHS

Kit for the preparation of Technetium Tc 99m Albumin Aggregated Injection: 2.5 mg of albumin aggregated as a non-radioactive white lyophilized powder in a multiple-dose reaction vial for radiolabeling with Sodium Pertechnetate Tc 99m Injection to prepare a suspension of Technetium Tc 99m Albumin Aggregated Injection. Each vial contains 3,000,000 to 8,000,000 particles.

4 CONTRAINDICATIONS

DRAXIMAGE MAA is contraindicated in patients with:

- Severe pulmonary hypertension *[see Warnings and Precautions (5.1)]*.
- A history of hypersensitivity to albumin human. Reactions have included anaphylaxis *[see Warnings and Precautions (5.2)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Patients with Pulmonary Hypertension

Deaths have been reported in patients with severe pulmonary hypertension after the administration of technetium Tc 99m albumin aggregated products *[see Adverse Reactions (6)]*. Assess patients for history or signs of pulmonary hypertension. DRAXIMAGE MAA is contraindicated in patients with severe pulmonary hypertension *[see Contraindications (4)].* Administer the lowest number of particles possible, have emergency resuscitation equipment available, and monitor patients for adverse reactions.

5.2 Hypersensitivity Reactions

Serious hypersensitivity reactions including anaphylaxis have been reported in patients treated with products containing albumin human, including DRAXIMAGE MAA *[see Adverse Reactions (6)]*. Obtain a history of allergy or hypersensitivity reactions. DRAXIMAGE MAA is contraindicated in patients with a history of hypersensitivity to albumin human *[see Contraindications (4)]*. Have emergency resuscitation equipment and trained personnel available prior to administration of Technetium Tc 99m Albumin Aggregated Injection. Monitor all patients for signs or symptoms of hypersensitivity reactions.

5.3 Risk of Temporary Impediment to Blood Flow in Patients with Right-to-Left Heart Shunts

In patients with right-to-left heart shunts, risk for temporary mechanical impediment to blood flow may exist due to the rapid entry of aggregated albumin into the systemic circulation. Administer the lowest possible number of particles of Technetium Tc 99m Albumin Aggregated Injection in these patients.

5.4 Radiation Risks

Technetium Tc 99m albumin aggregated contributes to a patient's overall long-term cumulative radiation exposure. Long-term cumulative radiation exposure is associated with an increased risk for cancer. Ensure safe handling to minimize radiation exposure to the patient and healthcare providers. Advise patients to hydrate before and after administration and to void frequently after administration *[see Dosage and Administration (2.2)].*

6 ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in the labeling:

- Patients with Pulmonary hypertension *[see Warnings and Precautions (5.1)]*.

- Hypersensitivity Reactions *[see Warnings and Precautions (5.2)]*.

The following adverse reactions associated with the use of technetium Tc 99m albumin aggregated products including DRAXIMAGE MAA were identified in clinical studies or postmarketing reports. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Cardiovascular Disorders: Deaths in patients with severe pulmonary hypertension

Immune System Disorders: Hypersensitivity reactions such as anaphylaxis, impairment of cardiac and circulatory functions in the form of changes in respiration, pulse, and blood pressure, chest pain and syncope, urticaria, reddening of the face, sweating, and nausea

Skin and Subcutaneous Tissue Disorders: Injection site reactions

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Available data with Technetium Tc 99m Albumin Aggregated Injection use in pregnant women are insufficient to evaluate for a drug-associated risk of major birth defects and miscarriage. Animal reproduction studies with technetium Tc 99m albumin aggregated have not been conducted Radiopharmaceuticals have the potential to cause fetal harm depending on the fetal stage of development and the magnitude of the radiation dose. The radiation exposure to the fetus from technetium Tc 99m albumin aggregated is expected to be low (less than 0.5 mGy) *(see Data).*

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defects, loss, or other adverse outcomes. In the U.S. general population the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies are 2% to 4% and 15% to 20%, respectively.

Data

Human Data

No adverse fetal effects of radiation risks have been identified for diagnostic procedures involving less than 50 mGy, which represents less than 10 mGy fetal doses.

8.2 Lactation

Risk Summary

Technetium-99m is present in breast milk. There are no data on the effects of technetium Tc 99m albumin aggregated on the breastfed infant or the effects on milk production. DRAXIMAGE MAA is used for imaging in infants with lung disease; exposure to technetium-99m via breastmilk is expected to be lower. Based on clinical guidelines, exposure of technetium Tc 99m albumin aggregated to a breastfed infant may be minimized by advising a lactating woman to temporarily discontinue breastfeeding and to pump and discard breast milk for a minimum of at least 24 hours after administration of Technetium Tc 99m Albumin Aggregated Injection.

The developmental and health benefits of breastfeeding should be considered along with a mother's clinical need for DRAXIMAGE MAA, any potential adverse effects on the breastfed child from technetium Tc 99m albumin aggregated or from the underlying maternal condition.

8.4 Pediatric Use

DRAXIMAGE MAA, after radiolabeling with technetium-99m, is indicated for lung scintigraphy as an adjunct in the evaluation of pulmonary perfusion in pediatric patients (birth to less than 17 years of age). The safety profile of Technetium Tc 99m Albumin Aggregated Injection in pediatric patients is similar to adults.

The safety and efficacy of DRAXIMAGE MAA have not been established for peritoneovenous shunt scintigraphy in pediatric patients.

8.5 Geriatric Use

No formal studies of DRAXIMAGE MAA in subjects aged 65 and over were performed to determine whether they respond differently from younger adult subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger adult patients. In general, dose selection for an elderly patient should be cautious; administering the low end of the particle dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

11 DESCRIPTION

11.1 Product Characteristics

DRAXIMAGE MAA contains albumin aggregated obtained by fractionating material (source blood, plasma, serum, or placentas) from healthy human donors. The macroaggregated albumin (MAA) particles are formed by denaturation of albumin human in a heating and aggregation process. Each vial contains 3,000,000 to 8,000,000 particles. By light microscopy, more than 90% of the particles are between 10 and 70 micrometers, while the typical average size is 20 to 40 micrometers; none is greater than 150 micrometers.

DRAXIMAGE MAA (kit for the preparation of technetium Tc 99m albumin aggregated) injection provides a sterile, non-pyrogenic, non-radioactive, white lyophilized powder supplied in a multiple-dose reaction vial, sealed under an atmosphere of nitrogen, for radiolabeling with Sodium Pertechnetate Tc 99m Injection to prepare Technetium Tc 99m Albumin Aggregated Injection, a radioactive diagnostic agent, for intravenous or intraperitoneal use.

Each reaction vial contains 2.5 mg of albumin aggregated, albumin human (5 mg), stannous chloride (0.06 mg minimum; 0.11 mg maximum stannous and stannic chloride) and sodium chloride (1.2 mg). Sodium hydroxide or hydrochloric acid has been added for pH adjustment. The pH is 5.2 to 6. It contains no preservative.

11.2 Physical Characteristics

Technetium-99m decays by isomeric transition with a physical half-life of 6.02 hours. The principal photon that is useful for detection and imaging studies is listed in Table 5.

Table 5. Principal Radiation Emission Data for Technetium-99m

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

11.3 External Radiation

The specific gamma ray constant for technetium-99m is 0.78 R/mCi-hr at 1 cm. The first half value layer is 0.017 cm of lead (Pb). A range of values for the relative attenuation of the radiation resulting from the interposition of various thicknesses of lead is shown in Table 6. For example, the use of 0.25 cm thickness of lead will attenuate the radiation emitted by a factor of about 1,000.

Table 6. 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 7.

Table 7. Physical Decay Chart for 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

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Following intravenous injection, more than 80% of the technetium Tc 99m albumin aggregated particles is trapped in the pulmonary alveolar capillary bed within 5 minutes.

Following intraperitoneal injection, technetium Tc 99m albumin aggregated mixes with the peritoneal fluid. Clearance from the peritoneal cavity varies from insignificant, which may occur with complete shunt blockage, to very rapid clearance with subsequent transfer into the systemic circulation when the shunt is patent.

12.2 Pharmacodynamics

The exposure-response relationship and time course of pharmacodynamic response for the safety and effectiveness of technetium Tc 99m albumin aggregated have not been fully characterized.

12.3 Pharmacokinetics

Distribution

Organ selectivity is a direct result of particle size. Albumin aggregated from 1 micrometer to 10 micrometers size are taken up by the reticuloendothelial system. Above 10 micrometers, the aggregates become lodged in the lung by trapping in the pulmonary alveolar capillary bed. Lung to liver ratios greater than 20:1 are obtained in the first few minutes post-injection. Distribution of particles in the lungs is a function of regional pulmonary blood flow.

The albumin aggregated is sufficiently fragile for the capillary micro-occlusion to be temporary. Erosion and fragmentation reduce the particle size, allowing passage of the aggregates through the pulmonary alveolar capillary bed. The fragments are then accumulated by the reticuloendothelial system.

Elimination

Elimination of the technetium Tc 99m albumin aggregated particles from the lungs occurs with a half-life of about 2 to 3 hours. Cumulative urinary excretion studies show an average of 20% elimination of the injected technetium Tc 99m albumin aggregated dose in 24 hours post-administration.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

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

16 HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

DRAXIMAGE MAA (kit for the preparation of technetium Tc 99m albumin aggregated) injection contains 2.5 mg of albumin aggregated as a white lyophilized powder in a multiple-dose reaction vial, sealed under an atmosphere of nitrogen, for radiolabeling with Sodium Pertechnetate Tc 99m Injection to prepare Technetium Tc 99m Albumin Aggregated Injection. It contains no preservative.

DRAXIMAGE MAA is supplied in a carton (NDC 65174-270-30) containing 30 multiple-dose reaction vials (NDC 65174-270-01) and 30 radioassay information labels.

Storage and Handling

Before radiolabeling, store the supplied reaction vials at 2 ºC to 25ºC (36 ºF to 77 ºF).

After radiolabeling with Sodium Pertechnetate Tc 99m Injection, store Technetium Tc 99m Albumin Aggregated Injection in a lead vial shield with cap in place, refrigerated at 2 ºC to 8 ºC (36 ºF to 46 ºF) when not in use. Use within 12 hours after radiolabeling *[see Dosage and Administration (2.5)].*

Dispose unused Technetium Tc 99m Albumin Aggregated Injection in compliance with the appropriate regulations of the government agency authorized to license the use of this radionuclide.

This preparation is approved for use by persons under license by the Nuclear Regulatory Commission or the relevant regulatory authority of an Agreement State.

17 PATIENT COUNSELING INFORMATION

Adequate Hydration

Instruct patients to drink a sufficient amount of water to ensure adequate hydration before their imaging and urge them to drink and urinate as often as possible during the first hours following the administration of Technetium Tc 99m Aggregated Albumin Injection, in order to reduce radiation exposure *[see Dosage and Administration (2.2)]*.

Pregnancy

Advise pregnant women of the risk of fetal exposure to radiation doses if they undergo a radionucleotide procedure *[see Use in Specific Populations (8.1)*].

Lactation

Advise a lactating woman to temporarily discontinue breastfeeding and to pump and discard breast milk for at least 24hours after Technetium Tc 99m Albumin Aggregated Injection administration to minimize radiation exposure to a breastfed infant *[see Use in Specific Populations (8.2)].*

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US License Number: 2186

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