HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use PULMOTECH™ MAA safely and effectively. See full prescribing information for PULMOTECH MAA.

PULMOTECH MAA (kit for the preparation of technetium Tc 99m albumin aggregated injection), for intravenous and intraperitoneal use.

Initial U.S. Approval: 1976

----------INDICATIONS AND USAGE----------
Technetium Tc 99m Albumin Aggregated Injection is a radioactive diagnostic agent indicated for:
- Lung scintigraphy as an adjunct in the evaluation of pulmonary perfusion in adults and pediatric patients. (1)
- Scintigraphy of peritoneovenous shunt as an aid in the evaluation of its patency in adults. (1)

---------- DOSAGE AND ADMINISTRATION----------
- For lung scintigraphy in adults, the recommended dose is 37 MBq to 148 MBq (1 mCi to 4 mCi) and 200,000 particles to 700,000 particles administered intravenously. (2.1)
- For scintigraphy of peritoneovenous shunts in adults, the recommended dose is 37 MBq to 111 MBq (1 mCi to 3 mCi) and 200,000 particles to 700,000 particles administered intraperitoneally. (2.1)
- For lung scintigraphy in pediatric patients, the recommended dose is 0.925 MBq/kg to 1.85 MBq/kg (0.025 mCi/kg to 0.05 mCi/kg) of body weight and 50,000 particles to 700,000 particles administered intravenously. In newborns, the recommended dose is 7.4 MBq to18.5 MBq (0.2 mCi to 0.5 mCi) and 10,000 particles to 50,000 particles administered intravenously. (2.1)

See Full Prescribing Information for preparation, administration, imaging, and radiation dosimetry information. (2.2, 2.3)

----------DOSAGE FORMS AND STRENGTHS ----------
Pulmotech MAA multiple-dose vial contains 2 mg of albumin aggregated as lyophilized powder. Upon radiolabeling with sodium pertechnetate Tc 99m injection solution, it provides an injectable suspension of technetium Tc 99m albumin aggregated. (3)

---------- CONTRAINDICATIONS----------
- Patients with severe pulmonary hypertension. (4)
- Patients with a history of hypersensitivity reactions to products containing human serum albumin. (4)

----------WARNINGS AND PRECAUTIONS ----------
- *Serious adverse reactions have been reported in patients with pulmonary hypertension.* (5.1)
- *Serious hypersensitivity reactions* have been reported. (5.2)

---------- ADVERSE REACTIONS ----------
Deaths after administration to patients with severe pulmonary hypertension and serious hypersensitivity reactions have been reported. (6)

To report SUSPECTED ADVERSE REACTIONS, contact CURIUM US LLC at 1-866-789-2211 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

---------- USE IN SPECIFIC POPULATIONS ----------
Lactation: Temporarily discontinue breastfeeding and discard breast milk for 13 hours after administration. (8.2)

See 17 for PATIENT COUNSELING INFORMATION

Revised: 03/2020

[redacted]

[redacted]

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

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Technetium Tc 99m Albumin Aggregated Injection is a radioactive diagnostic agent indicated for:

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

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dosage and Administration

Adult Patients
The recommended intravenous dose range for adult patients for lung imaging is 37 MBq to 148 MBq (1 mCi to 4 mCi) and 200,000 to 700,000 particles of Technetium Tc 99m Albumin Aggregated Injection after preparation with oxidant-free Sodium Pertechnetate Tc 99m Injection.

The recommended intraperitoneal dosage range for adult patients for peritoneovenous shunt patency evaluation is 37 MBq to 111 MBq (1 mCi to 3 mCi) and 200,000 to 700,00 particles. Adequate measures should be taken to assure uniform mixing with peritoneal fluid. Serial images of both the shunt and target organ should be obtained and correlated with other clinical findings. Alternatively, the drug may be administered by percutaneous transtubal injection. The recommended percutaneous transtubal dosage range for adult patients is 12 MBq to 37 MBq (0.3 mCi to 1 mCi) in a volume not to exceed 0.5 mL.

The recommended range of particle numbers per single injection is 200,000 to 700,000 with the recommended number of approximately 350,000. Depending on the activity added and volume of the final reconstituted 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 technetium Tc 99m that has occurred. The number of particles in any dose and volume to be administrated 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_{Tc} = volume of solution added to reaction vial
D = desired dose to be administered in MBq (mCi)
C = concentration at calibration time of Sodium Pertechnetate solution to be added to the reaction vial in MBq/mL (mCi/mL)
V_a = volume to be administered in mL
P = number of particles in dose to be administered
Fr = fraction of Technetium Tc 99m remaining after the time of calibration (Table 7)
N = number of particles per vial. The number of particles per vial for the lot is located on the vial label.

Pediatric Patients
In pediatric patients, the recommended intravenous dose for perfusion lung imaging is in the range of 0.925 MBq/kg to 1.85 MBq/kg (0.025 mCi/kg to 0.05 mCi/kg) of body weight; a usual dose is 1.11 MBq/kg (0.03 mCi/kg), except in newborns, in whom the administered dose should be 7.4 MBq to 18.5 MBq (0.2 mCi to 0.5 mCi). Not less than the minimum dose of 7.4 MBq (0.2 mCi) should be employed for this procedure. The number of particles varies with age and weight as shown in Table 1.

Table 1 – Pediatric Patients: Particle Number and Dose for Lung Scintigraphy

Age	Newborn		1 year		5 years		10 years		15 years	
Weight (kg)	3.5		12.1		20.3		33.5		55	
Maximal recommended dose	MBq	mCi	MBq	mCi	MBq	mCi	MBq	mCi	MBq	mCi
	18.5	0.5	22.2	0.6	37	1	62.9	1.7	103.6	2.8
Range of particles administered	10,000 to 50,000		50,000 to 150,000		200,000 to 300,000		200,000 to 300,000		200,000 to 700,000	

Adults and Pediatric Patients
Visually inspect for particulate matter and discoloration prior to administration.

Measure the patient dose by a suitable radioactivity calibration system immediately prior to administration. Mix the contents of the vial by gentle inversion just prior to withdrawing a patient dose.

Mix the contents of the syringe just before injection. If blood is drawn into the syringe, any unnecessary delay prior to injection may lead to clot formation. For optimal results and because of rapid lung clearance of the radiopharmaceutical, position the patient under the imaging apparatus before administration. Slow injection is recommended. Lung imaging may begin immediately after intravenous injection of the radiopharmaceutical. Due to high kidney uptake, imaging later than one-half hour after administration will yield poor results.

2.2 Radiation Dosimetry

Adult Patients
The estimated absorbed radiation doses[3] to an average adult patient (70 kg) from an intravenous administration of 148 MBq (4 mCi) of Technetium Tc 99m

Albumin Aggregated Injection are shown in Table 2.

Table 2 – Adults: Radiation Absorbed Doses for Lung Scintigraphy

Organs	mGy/148 MBq	rad/4 mCi
Total body	0.6	0.06
Lungs	8.8	0.88
Liver	0.72	0.072
Spleen	0.68	0.068
Kidneys	0.44	0.044
Bladder wall		
3.5 hr. void	1.2	0.12
4.8 hr. void	2.2	0.22
Testes		
3.5 hr. void	0.24	0.024
4.8 hr. void	0.26	0.026
Ovaries		
3.5 hr. void	0.3	0.03
4.8 hr. void	0.34	0.034

Table 3 shows the radiation absorbed dose resulting from the intraperitoneal administration of 111 MBq (3 mCi) of Technetium Tc 99m Albumin Aggregated.

Table 3 – Adults: Radiation Absorbed Doses[1] for Intraperitoneal Shunt Scintigraphy

Organs	Shunt Patency (Open)		Shunt Patency (Closed)	
	mGy	Rad	mGy	Rad
Lung	6.9	0.69	1.68	0.168
Ovaries & Testes	0.18 to 0.3	0.018 to 0.03	1.68	0.168
Organs in the peritoneal cavity	-	-	1.68	0.168
Total body	0.36	0.036	0.57	0.057

*Assumptions: calculations for the radiation absorbed dose are based upon an effective half-time of 3 hours for the open shunt and a physical half-life of 6 hours for the closed shunt and an even distribution of the radiopharmaceutical in the peritoneal cavity with no biological clearance.

Pediatric Patients

In pediatric patients, the radiation absorbed doses using the maximum recommended dose for lung imaging are based on 1.85 MBq (0.05 mCi) per kilogram of body weight (except in the newborns where the maximum recommended dose of 18.5 MBq (0.5 mCi) is used) and are shown in Table 4.

Table 4 – Pediatric Patients: Radiation Absorbed Doses for Lung Scintigraphy[2,3]

Age	Newborn		1 year		5 years		10 years		15 years	
	mGy	rad	mGy	Rad	mGy	rad	mGy	rad	mGy	Rad
ORGANS										
Total body	0.6	0.06	0.3	0.03	0.31	0.031	0.48	0.048	0.41	0.041
Lungs	19	1.9	6.6	0.66	5.8	0.58	8.7	0.87	7.7	0.77
Liver	1.4	0.14	0.6	0.06	0.62	0.062	1.8	0.18	1.2	0.12
Bladder wall	2.1	0.21[(1)]	1.5	0.15[(1)]	3.1	0.31[(2)]	3.9	0.39[(2)]	4.1	0.41
Ovaries	0.38	0.038	0.2	0.02	0.19	0.019	0.44	0.044	0.41	0.041
Testes	0.31	0.031	0.13	0.013	0.19	0.019	0.2	0.02	0.36	0.036

[(1)] 2 hour voiding interval
[(2)] 4.8 hour voiding interval

2.3 Directions for Preparation

Procedural Precautions

- Perform all transfer and vial stopper entries using aseptic techniques.
- Wear waterproof gloves during the entire preparation procedure and during subsequent patient dose withdrawals from the Pulmotech MAA vial.
- Make all transfers of sodium pertechnetate Tc 99m injection solution during the preparation procedure with an adequately shielded syringe.
- Keep the Radioactive Preparation in the Dispensing Vial Shield described below (with cap in place) during the useful life of the Radioactive Preparation. Make all withdrawals and injections of the Radioactive Preparation with an adequately shielded syringe.

Procedure for the Preparation of Technetium Tc 99m Albumin Aggregated

1. If Pulmotech MAA vials are stored in the refrigerator, remove a vial and allow the contents to come to room temperature for approximately 5 minutes.

2. Remove the protective disc from the Pulmotech MAA vial and swab the rubber septum with an alcohol swab or a suitable bacteriostatic agent to disinfect the surface.

3. Place the vial in a suitable dispensing vial shield fitted with a shielded cap.

4. Calculate the amount of sodium pertechnetate Tc 99m injection solution (2 mL to 13 mL) to be added to the Pulmotech MAA vial. During or prior

to addition of technetium Tc 99m solution do not vent the Pulmotech MAA vial. In choosing the amount of technetium Tc 99m radioactivity to be used in the preparation of technetium Tc 99m albumin aggregated ensure that the radioactive dose will contain the desired number of MAA particles, while taking into account the number of patients, administered radioactive dose, radioactive decay. The recommended maximum amount of technetium Tc 99m to be added to the Pulmotech vial is 6.85 GBq (185 mCi**).** Calculate (see section 2.1) the amount of radioactivity per vial required to be added to maintain the number of particles per dose within a recommended range [for adults 200,000 to 700,000, and for pediatric patients as per Table 1].

5. After adding sodium pertechnetate Tc 99m injection solution to the Pulmotech MAA vial in the dispensing Vial shield (with cap in place), mix the contents by agitation and allow to stand for a minimum of 15 minutes at room temperature. Once prepared the product will have a turbid white appearance.

6. Assay the product in a suitable dose calibrator and record the activity of the technetium Tc 99m albumin aggregated, total suspension volume, number of Tc 99m MAA particles, radioactive concentration, time and date of preparation, onto the radio-assay information label and attach it to the dispensing vial shield. 0.9% Sodium Chloride Injection, USP may be used as a diluent for the radiolabeled product to achieve the desired number of particles and radioactivity.

7. Prior to withdrawing a dose, gently agitate the contents of the radiolabeled Pulmotech MAA vial to resuspend any settled technetium Tc 99m albumin aggregated particles. Failure to mix the reaction vial contents adequately before use may result in a non-homogenous suspension with a resulting non-uniform distribution of radioactivity in the lung. Withdrawals for administration must be made aseptically using a sterile needle (18 to 21 gauge) and syringe. Since the vials contain nitrogen to prevent oxidation of the complex, the vials should not be vented. If repeated withdrawals are made from the vial, the contents should not be replaced with air.

8. Store the radiolabeled Pulmotech MAA vial in the dispensing vial shield in a refrigerator at 2° to 8°C (36° to 46°F). Use radiolabeled Pulmotech MAA within 18 hours from the time of preparation. Discard unused product.

3 DOSAGE FORMS AND STRENGTHS

Pulmotech MAA multiple-dose vial contains 2 mg of albumin aggregated as lyophilized powder. Radiolabeling with sodium pertechnetate Tc 99m injection solution provides an injectable suspension of technetium Tc 99m albumin aggregated. The radioactive dose for an adult is intended to contain 200,000 particles to 700,000 particles of technetium Tc 99m albumin aggregated with the target dose of approximately 350,000. Depending on the activity added and volume of the final reconstituted product, the volume of the dose may vary from 0.2 mL to 1.9 mL.

4 CONTRAINDICATIONS

Technetium Tc 99m Albumin Aggregated Injection is contraindicated in patients with:

- Severe pulmonary hypertension *[see Adverse Reactions (6)].*
- Prior hypersensitivity to products containing human serum albumin *[see Adverse Reactions (6)].*

5 WARNINGS AND PRECAUTIONS

5.1 Pulmonary Hypertension

Serious adverse reactions have been reported in patients with pulmonary hypertension after Technetium Tc 99m Albumin Aggregated Injection. Assess patients for history or signs of pulmonary hypertension, administer the lowest number of particles possible, have emergency resuscitation equipment available and monitor patients for adverse reactions. *[see Adverse Reactions (6)].*

5.2 Hypersensitivity Reactions

Serious reactions have been reported in patients with hypersensitivity to products containing human serum albumin, including Technetium Tc 99m Albumin Aggregated Injection. Obtain a history of allergy or hypersensitivity reactions and always have emergency resuscitation equipment and trained personnel available prior to administration of Technetium Tc 99m Albumin Aggregated Injection. Monitor all patients for hypersensitivity reactions.

5.3 Radiation Risks

The contents of the supplied Pulmotech MAA vials are not radioactive. However, after adding sodium pertechnetate Tc 99m injection solution to the vial, adequate shielding of the final preparation must be maintained.

As in the use of any radioactive material, care should be taken to minimize radiation exposure to the patient and to insure minimum radiation exposure to occupational workers.

Radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radionuclides and whose experience and training have been approved by the appropriate governmental agency authorized to license the use of radionuclides.

6 ADVERSE REACTIONS

Deaths occurring after the administration of aggregated albumin to patients with severe pulmonary hypertension and serious hypersensitivity reactions to preparations of Technetium Tc 99m Albumin Aggregated Injection have been reported.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Available data from case reports on Technetium Tc 99m Albumin Aggregated Injection are insufficient to evaluate drug-associated risks of major birth defects, miscarriage, or adverse maternal or fetal outcomes. Animal reproduction studies with technetium Tc 99m Albumin Aggregated Injection have not been conducted. All radiopharmaceuticals have the potential to cause fetal harm depending on the fetal stage of development and the magnitude of the radiation dose. If considering Technetium Tc 99m Albumin Aggregated Injection administration to a pregnant woman, inform the patient about the potential for adverse pregnancy outcomes based on the radiation dose from Technetium Tc 99m Albumin Aggregated Injection and the gestational timing of exposure.

All pregnancies have a background risk of birth defect, 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 is 2% to 4% and 15% to 20%, respectively.

8.2 Lactation

Risk Summary
Data available in the published literature demonstrate the presence of pertechnetate in human milk. There are no data available on the effects of Tc-99m Albumin Aggregated Injection on the breastfed infant or the effects on milk production. Exposure of pertechnetate to a breast fed infant can be minimized by temporary discontinuation of breastfeeding *(see Clinical Considerations).* The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for a Technetium Tc 99m Albumin Aggregated Injection, any potential adverse effects on the breastfed child from radioactivity and from the underlying maternal condition.

Clinical Considerations
To decrease radiation exposure to the breastfed infant, advise a lactating woman to pump and discard breast milk after the administration of Technetium Tc 99m Albumin Aggregated Injection for 13 hours, where the duration corresponds to the typical range of administered activity, 37 to 148 MBq (1 to 4 mCi). During the period of interruption, the breasts should be emptied regularly and completely. The milk that is pumped by the mother during the time of breastfeeding interruption can either be discarded or stored refrigerated and given to the infant after 10 physical half-lives, or about 60 hours, have elapsed.

8.4 Pediatric Use

Technetium Tc 99m Albumin Aggregated Injection is indicated for lung scintigraphy as an adjunct in the evaluation of pulmonary perfusion in pediatric patients *[see Dosage and Administration (2)]*. The safety profile of Technetium Tc99m Albumin Aggregated Injection is similar to the one in adults.

11 DESCRIPTION

Pulmotech MAA (kit for the preparation of technetium Tc 99m albumin aggregated injection), when prepared with sodium pertechnetate Tc 99m injection, provides Technetium Tc 99m Albumin Aggregated Injection. Pulmotech MAA contains macroaggregates of U.S.-licensed human serum albumin (non-reactive when tested for hepatitis B antigen (HB_SAg) by enzyme immunoassay). The macroaggregated albumin (MAA) is obtained by heat denaturation of stannous chloride treated human serum albumin under controlled conditions.

Upon radiolabeling with sodium pertechnetate Tc 99m injection solution, the stannous reduced Tc99m binds to the aggregated albumin to provide technetium Tc 99m albumin aggregated. The particle size distribution of the aggregated albumin is such that not less than 90 percent are 10 to 90 microns in size. There are no aggregated albumin particles greater than 150 microns in size as determined by circular equivalents.

Pulmotech MAA is provided as a 15 mL multiple-dose glass vial containing white lyophilized powder. The contents of the vial are under nitrogen. Each vial contains 2 mg of albumin aggregated, 7.1 mg of albumin human (soluble), 0.22 mg of maximum total tin (as $SnCl_2 \cdot 2H_2O$), 0.1 mg (minimum) stannous chloride, and 9 mg of sodium chloride. Hydrochloric acid is added for pH adjustment and the pH of the reconstituted solution is between 5 and 7. The kit does not contain any bacteriostatic agent.

11.1 Physical Characteristics

Technetium Tc 99m decays by isomeric transition with a physical half-life of 6.02 hours.[4] The principal photon that is useful for detection and imaging is listed in Table 5.

Table 5 – Principal Radiation Emission Data[4]

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

11.2 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 this radionuclide that results from interposition of various thicknesses of Pb is shown in Table 6. For example, the use of 0.25 cm of Pb will decrease the external radiation exposure by a factor of about 1000.

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 time intervals after the time of calibration are shown in Table 7.

Table 7 – Physical Decay Chart: Technetium Tc 99m Half-Life 6.02 Hours

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

*Calibration Time

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Within 1 to 5 minutes of intravenous injection, over 90 percent of the technetium Tc 99m albumin aggregated particles are trapped in the arterioles and capillaries of the lung.

Following intraperitoneal administration of Technetium Tc 99m Albumin Aggregated Injection, the radiopharmaceutical 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.

12.3 Pharmacokinetics

Distribution

Organ selectivity is a direct result of particle size. At 10 microns and below, the albumin aggregates are taken up by the reticuloendothelial system. Above 10 to 15 microns, the aggregates become lodged in the lung capillaries by a purely mechanical process. Distribution of aggregated albumin 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 then accumulate in the reticuloendothelial system.

Elimination

Elimination of the Technetium Tc 99m Albumin Aggregates from the normal and abnormal human lungs occurs with a biological half-life of 10.8 hours (range 6.9 to 19 hours, n=5).

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

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

15 REFERENCES

1. Method of calculation: “S” Absorbed Dose per Unit Cumulated Activity for Selected Radionuclides and Organs, MIRD Pamphlet No. 11 (1975).
2. Used biologic data from Kaul *et al*., Berlin, 1973.
3. For the newborn, 1-year old, and 5-year old, the “S” values calculated form the preliminary phantoms of ORNL were used. The 10-year old, 15-year old and adult “S” values are from Henrichs, *et al*., Berlin, 1980.

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

Pulmotech MAA (kit for the preparation of technetium Tc 99m albumin aggregated injection) is supplied either as a 5 vial clam shell (NDC 69945-139-20) or as a carton of 30 vials (NDC 69945-139-40).

Each 5 vial kit contains 5 multiple dose Pulmotech MAA vials, 1 prescribing information and 5 radio assay information labels. Each 30 vial carton contains 30 multiple dose Pulmotech MAA vials, 1 prescribing information and 30 radio assay information labels.

16.2 Storage and Disposal

Store Pulmotech MAA (kit for the preparation of Tc 99m albumin aggregated injection) at 2° to 25°C (36° to 77ºF) before preparation (radiolabeling).

After, preparation with sodium pertechnetate Tc 99m injection, store radiolabeled technetium Tc 99m albumin aggregated Injection in a refrigerator at 2° to 8°C (36° to 46ºF).

Do not use and discard radiolabeled Pulmotech MAA at 18 hours after preparation.

17 PATIENT COUNSELING INFORMATION

Adequate Hydration
Advise patients to drink a sufficient amount of water to ensure adequate hydration before their study and urge them to drink and urinate as often as possible during the first hours following the administration of Technetium Tc 99m Albumin Aggregated Injection in order to reduce radiation exposure.

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 interrupt breastfeeding and pump and discard breast milk for 13 hours after Technetium Tc 99m Albumin Aggregated Injection administration in order to minimize radiation exposure to a breastfed infant *[see Use in Specific Populations (8.2)]*.

Pulmotech is a trademark of a Curium company.

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