PULMOTECH MAA- kit for the preparation of technetium tc 99m albumin aggregated injection, powder, lyophilized, for suspension
Curium US LLC

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 or intraperitoneal use.
Initial U.S. Approval: 2020

RECENT MAJOR CHANGES

Dosage and Administration, Directions for Drug Preparation and Handling (2.5) 10/2025

INDICATIONS AND USAGE

PULMOTECH MAA, after radiolabeling with technetium-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 perfusion scintigraphy, the following recommended activity is administered by intravenous injection.
  • Adults: 37 MBq to 148 MBq (1 mCi to 4 mCi) and 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 peritoneovenous shunts scintigraphy in adults: 37 MBq to 111 MBq (1 mCi to 3 mCi) and 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 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 containing up to 6.85 MBq (185 mCi) in 2 to 13 mL volume at time of preparation. Each vial contains 2,000,000 to 4,000,000 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 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. 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: 10/2025

FULL PRESCRIBING INFORMATION: CONTENTS*

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

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

PULMOTECH MAA, after radiolabeling with technetium-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 adults.

2 DOSAGE AND ADMINISTRATION

2.1 Radiation Safety – Drug Handling

After radiolabeling of PULMOTECH 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 range of particle numbers per single injection should be 200,000 to 700,000 with the recommended number of 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 technetium-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_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)

Fr = fraction of Technetium-99m remaining after the time of calibration from Table 6 *[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 the lot is located on the vial label.

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 dose for lung perfusion scintigraphy in this age 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 shown 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	
Maximal recommended activity	MBq 103.6	mCi 2.8	MBq 62.9	mCi 1.7	MBq 37	mCi 1	MBq 22.2	mCi 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 and the number of particles per single injection should be 200,000 to 700,000 with the recommended number of 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 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

- 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 during the preparation procedure with an adequately shielded syringe.
- Keep the prepared Technetium Tc 99m Albumin Aggregated Injection 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 Technetium Tc 99m Albumin Aggregated Injection with an adequately shielded syringe.

Procedure for the Preparation, Storage, and Handling of Technetium Tc 99m Albumin Aggregated Injection

1. If PULMOTECH MAA reaction 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 cap from the reaction 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 (2 mL to 13 mL) to be added to the reaction vial. In choosing the amount of Sodium Pertechnetate Tc 99m Injection to be used in the preparation of Technetium Tc 99m Albumin Aggregated Injection ensure that the radioactive dose will contain the desired number of macroaggregated albumin (MAA) particles, while taking into account the number of patients, administered activity, and radioactive decay. The recommended maximum activity of Sodium Pertechnetate Tc 99m Injection to be added to the reaction vial is 6.85 GBq (185 mCi). Calculate 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 *[see Dosage and Administration (2.3, 2.4)].*

5. During or prior to addition of Sodium Pertechnetate Tc 99m Injection do not vent the reaction vial.
6. After adding Sodium Pertechnetate Tc 99m Injection to the reaction vial in the dispensing vial shield (with cap in place), mix the contents by inverting the vial at a frequency of one (1) inversion per second for 2 minutes (approximately 120 inversions total) and allow to stand for a minimum of 15 minutes at room temperature. Once prepared the product will have a turbid white appearance.
7. Assay the product in a suitable dose calibrator and record the total activity of Technetium Tc 99m Albumin Aggregated Injection, total volume, number of MAA particles, radioactive concentration, time and date of preparation, onto the radioassay 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.
8. 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.
   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.
9. Store the radiolabeled PULMOTECH MAA in the dispensing vial shield in a refrigerator at 2°C to 8°C (36°F to 46°F). Use within 18 hours from the time of radiolabeling. Dispose unused radiolabeled PULMOTECH MAA 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 injection of the radiopharmaceutical. 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 2.

Table 2. 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	8.11	--	--	--	67.6	114
2 hour void	14.9	--	62	83.8	--	--
4.8 hour void	--	39.6	--	--	--	--
No voiding intervals						
Testes	1.62	--	--	--	--	--
2 hour void	1.76	--	--	--	--	--
4.8 hour void	--	3.47	3.18	5.14	5.86	16.8
No voiding intervals						
Ovaries	2.03	--	--	--	--	--
2 hour void	2.3	--	--	--	--	--
4.8 hour void	--	3.96	7	5.14	9.01	20.5
No voiding intervals						

*--: Not available

Intraperitoneal Administration

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

Table 3. 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 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 containing up to 6.85 MBq (185 mCi) in 2 to 13 mL volume at time of preparation. Each vial contains 2,000,000 to 4,000,000 particles.

4 CONTRAINDICATIONS

PULMOTECH 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. PULMOTECH 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 PULMOTECH MAA *[see Adverse Reactions (6)].* Obtain a history of allergy or hypersensitivity reactions. PULMOTECH 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 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 health care 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 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 PULMOTECH MAA have been 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 from case reports on Technetium Tc 99m Albumin Aggregated Injection use 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 have not been conducted. Although all 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 0.50 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 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.

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. PULMOTECH 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 PULMOTECH 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

PULMOTECH MAA, after radiolabeling with technetium Tc-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 Tc99m Albumin Aggregated Injection is similar to the one in adults.

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

8.5 Geriatric Use

No formal studies of PULMOTECH 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

PULMOTECH 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 heat denaturation of stannous chloride treated albumin human under controlled conditions. Each vial contains 2,000,000 to 4,000,000 particles. The particle size distribution of the aggregated albumin is such that not less than 90% are 10 to 90 micrometers in size. There are no aggregated albumin particles greater than 150 micrometers in size as determined by circular equivalents.

PULMOTECH MAA (kit for the preparation of technetium Tc 99m albumin aggregated) injection provides a sterile, non-pyrogenic, non-radioactive, 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, a radioactive diagnostic agent, for intravenous or intraperitoneal use.

Each reaction vial contains 2 mg of albumin aggregated, albumin human (7.1 mg), stannous chloride (0.1 mg minimum; 0.22 mg maximum stannous and stannic), sodium chloride (9 mg). Hydrochloric acid may have been added for pH adjustment. The pH is between 5 and 7. It contains no preservatives.

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 is listed in Table 4.

Table 4 – Principal Radiation Emission Data for Technetium-99m

Radiation	Mean % per Disintegration	Energy (keV)
Gamma-2	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 thickness of lead (Pb) for technetium-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 5. For example, the use of 0.25 cm of Pb will decrease the external radiation exposure by a factor of about 1,000.

Table 5 – 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 6.

Table 6– Physical Decay Chart for Technetium-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, 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. At 10 micrometer and below, the albumin aggregates are taken up by the reticuloendothelial system. Above 10 to 15 micrometer, 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 aggregated particles 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.

16 HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

PULMOTECH MAA (kit for the preparation of technetium Tc 99m albumin aggregated) injection contains 2 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.

PULMOTECH MAA is supplied as:
- a carton (clam shell) of 5 vials (NDC 69945-139-20)
- a carton of 30 vials (NDC 69945-139-40)

Each 5-vial carton contains 5 multiple-dose reaction vials and 5 radioassay information labels. Each 30-vial carton contains 30 multiple-dose reaction vials and 30 radioassay information labels.

Storage and Handling

Before radiolabeling, store supplied reaction vials at 2°C to 25°C (36°F to 77ºF).

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°C to 8°C (36°F to 46ºF) when not in use. Use within 18 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

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

Manufactured by:
CIS bio International
Route Departementale 306
Gif-sur-Yvette, Ile-de-France 91190, France

U.S License No. 2204

Distributed by:
Curium US LLC
2703 Wagner Place
Maryland Heights, MO 63043

A139I0 Curium™

PRINCIPAL DISPLAY PANEL

Kit for the Preparation of Technetium Tc 99m Albumin Aggregated

NDC 69945-139-10 Pulmotech™ MAA Sterile, Multiple-Dose Vial

Rx only Injection

For Intravenous or Intraperitoneal use after radiolabeling with Sodium Pertechnetate Tc 99m Injection.

Each reaction vial contains 2 mg of albumin aggregated.

STORAGE: Before radiolabeling, store at 2°C to 25°C (36°F to 77°F). **After radiolabeling**, store vial in a suitable lead shield in a refrigerator at 2°C to 8°C (36°F to 46°F). Use within 18 hours after radiolabeling.

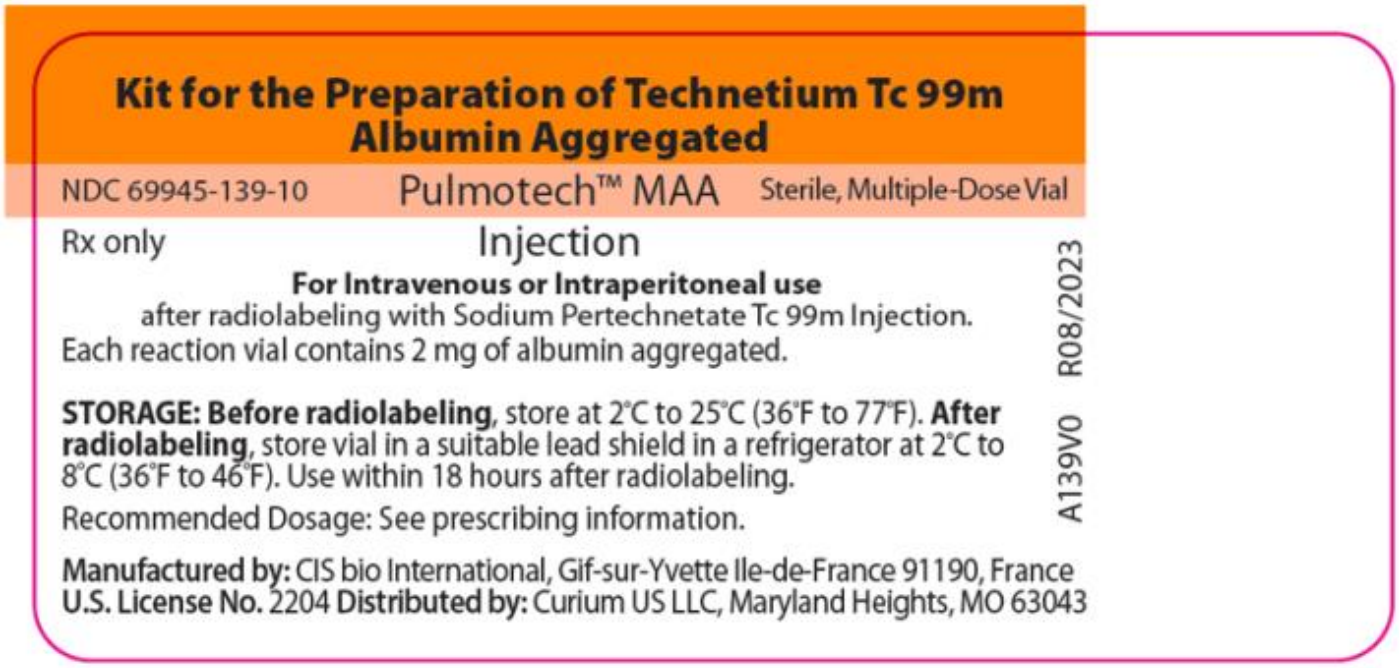
Recommended Dosage: See prescribing information.

Manufactured by: CIS bio International, Gif-sur-Yvette Ile-de-France 91190, France

U.S. License No. 2204 **Distributed by:** Curium US LLC, Maryland Heights, MO 63043

A139V0

R08/2023



PRINCIPAL DISPLAY PANEL

NDC 69945-139-40

Kit for the Preparation of Technetium Tc 99m Albumin Aggregated Pulmotech™ MAA

Injection

For Intravenous or Intraperitoneal use after radiolabeling with Sodium Pertechnetate Tc 99m Injection.

Rx only

STORAGE:

Before radiolabeling, store at 2°C to 25°C (36°F to 77°F). **After radiolabeling,** store vial in a suitable lead shield in a refrigerator at 2°C to 8°C (36°F to 46°F). Use within 18 hours after radiolabeling.

CURIUM™

30 Multiple-Dose Vials

PINCH AT CORNERS / PULL OUT

Recommended Dosage: See prescribing information.

CARTON CONTAINS:

30 sterile, multiple-dose reaction vials

30 radioassay information labels

1 Prescribing Information

Each reaction vial contains 2 mg of albumin aggregated, albumin human (7.1 mg), stannous chloride (0.1 mg minimum; 0.22 mg maximum stannous and stannic), and

sodium chloride (9 mg). Hydrochloric acid has been used for pH adjustment; Sealed under nitrogen; Contains no preservative.

Manufactured by:

CIS bio International

Route Departementale 306

Gif-sur-Yvette Ile-de-France 91190, France

U.S. License No. 2204

Distributed by:

Curium US LLC

2703 Wagner Place

Maryland Heights, MO 63043

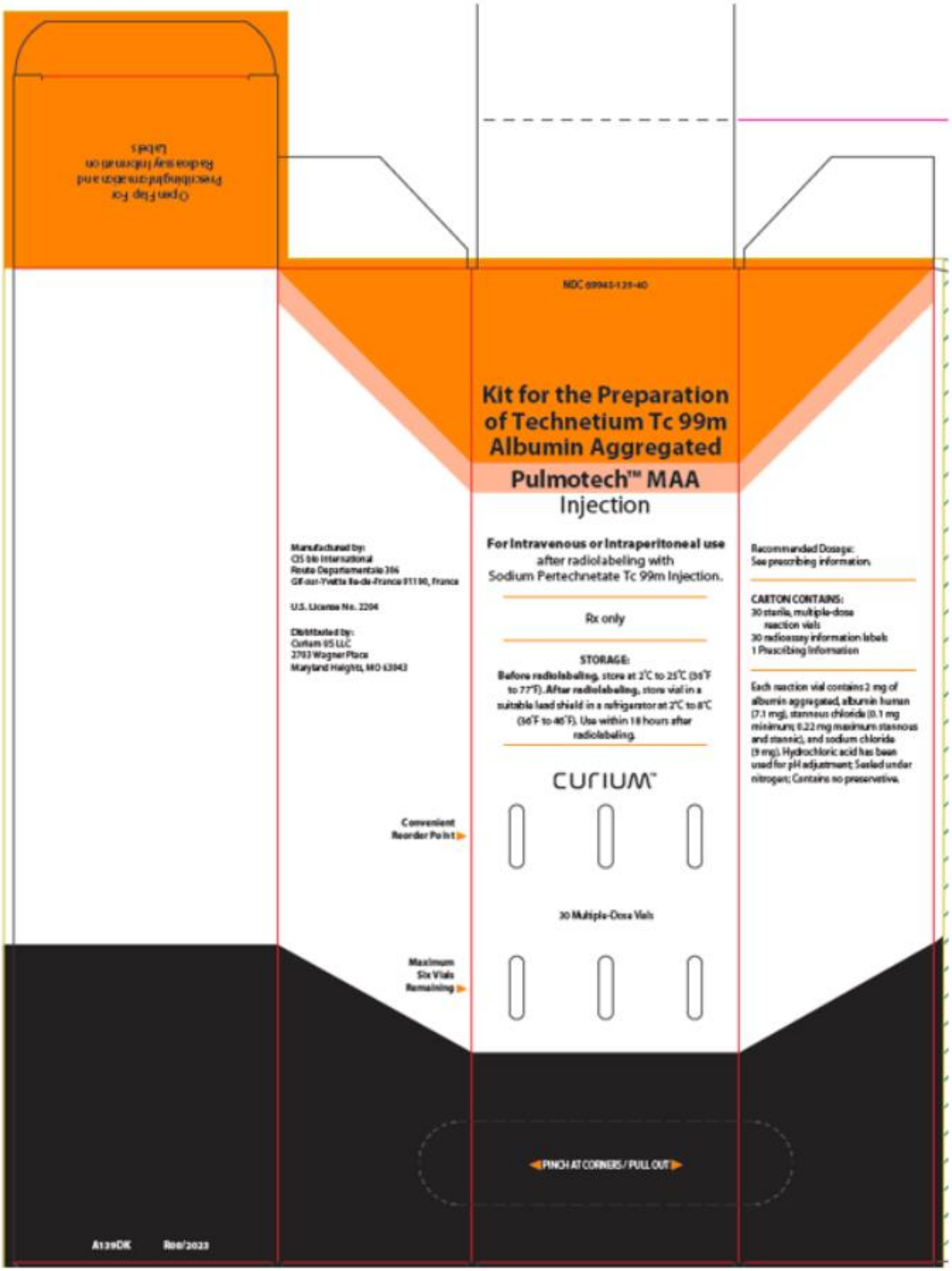
Convenient Reorder Point

Maximum Six Vials Remaining

Open Flap For Prescribing Information and Radioassay Information Labels

A139DK

R08/2023


Open Flap For Prescribing Information and Radioassay Information on Labels
NDC 69945-139-40
Kit for the Preparation of Technetium Tc 99m Albumin Aggregated
Pulmotech™ MAA
Injection
For Intravenous or Intraperitoneal use
after radiolabeling with
Sodium Pertechnetate Tc 99m Injection.
Rx only
STORAGE:
Before radiolabeling, store at 2°C to 25°C (36°F to 77°F). After radiolabeling, store vial in a suitable lead shield in a refrigerator at 2°C to 8°C (36°F to 46°F). Use within 18 hours after radiolabeling.
Manufactured by:
CIS bio International
Route Departementale 306
Gif-sur-Yvette Ile-de-France 91190, France
U.S. License No. 2204
Distributed by:
Curium US LLC
2703 Wagner Place
Maryland Heights, MO 63043
CURIUM™
Convenient Reorder Point
30 Multiple-Dose Vials
Maximum Six Vials Remaining
Recommended Dosage:
See prescribing information.
CARTON CONTAINS:
30 sterile, multiple-dose reaction vials
30 radioassay information labels
1 Prescribing Information
Each reaction vial contains 2 mg of albumin aggregated, albumin human (7.1 mg), stannous chloride (0.1 mg minimum; 0.22 mg maximum stannous and stannic), and sodium chloride (9 mg). Hydrochloric acid has been used for pH adjustment; Sealed under nitrogen; Contains no preservative.
PINCH AT CORNERS / PULL OUT
A139DK Rev/2023

PULMOTECH MAA

kit for the preparation of technetium tc 99m albumin aggregated injection, powder, lyophilized, for suspension

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:69945-139
Route of Administration	INTRAPERITONEAL, INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALBUMIN AGGREGATED (UNII: 799C8VF17R) (ALBUMIN AGGREGATED - UNII:799C8VF17R)	ALBUMIN AGGREGATED	2 mg in 15 mL

Inactive Ingredients

Ingredient Name	Strength
ALBUMIN HUMAN (UNII: ZIF514RVZR)	7.1 mg in 15 mL
STANNOUS CHLORIDE (UNII: 1BQV3749L5)	0.1 mg in 15 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	9 mg in 15 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69945-139-20	5 in 1 CELLO PACK	03/20/2020	
1	NDC:69945-139-10	15 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
2	NDC:69945-139-40	30 in 1 CARTON	03/20/2020	
2	NDC:69945-139-10	15 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA210089	03/20/2020	

Labeler - Curium US LLC (079875617)

Revised: 10/2025 Curium US LLC