KIT FOR THE PREPARTION OF TECHNETIUM TC99M SULFUR COLLOID- technetium tc 99m sulfur colloid

Sun Pharmaceutical Industries, Inc.

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use Kit for the Preparation of Technetium Tc 99m Sulfur Colloid Injection.

See full prescribing information for Kit for the Preparation of Technetium Tc 99m Sulfur Colloid Injection.

Kit for the Preparation of Technetium Tc 99m Sulfur Colloid Injection for Subcutaneous, Intraperitoneal, Intravenous and Oral Use.

Initial U.S. Approval: 1978

INDICATIONS AND USAGE

Technetium Tc 99m Sulfur Colloid Injection is a radioactive diagnostic agent indicated (1):
In adults, to assist in the:

- localization of lymph nodes draining a primary tumor in patients with breast cancer or malignant melanoma when used with a hand-held gamma counter.
- evaluation of peritoneo-venous (LeVeen) shunt patency in adults.

In adults and pediatric patients, for:

- imaging areas of functioning reticuloendothelial cells in the liver, spleen and bone marrow.
- studies of esophageal transit and gastroesophageal reflux, and detection of pulmonary aspiration of gastric contents.

DOSAGE AND ADMINISTRATION

Minimize Tc99m Sulfur Colloid radiation exposure and measure patient doses immediately before administration.

- Breast cancer or malignant melanoma setting: by subcutaneous injection, 3.7 to 37 MBq (0.1 to 1 mCi in volumes ranging from 0.1 to 1 mL) (2.1).
- Peritoneo-venous (LeVeen) shunt setting in adults: (2.1)
    - by intraperitoneal injection: 37 to 111 MBq (1 to 3 mCi);
    - by percutaneous transtubal injection: 12 to 37 MBq (0.3 to 1 mCi) in a volume not to exceed 0.5 mL.
- Imaging areas of functioning reticuloendothelial cells by intravenous injection (2.1):
  In adults:
- Liver/spleen imaging: 37 to 296 MBq (1 to 8 mCi);
- Bone marrow imaging: 111 to 444 MBq (3 to 12 mCi);
  In pediatric patients:
- Liver/spleen imaging in newborns: 7.4 to 18.5 MBq (0.2 to 0.5 mCi);
- Liver/spleen imaging in children: 0.56 to 2.78 MBq (0.015 to 0.075 mCi) per kg of body weight (BW);
- Bone marrow imaging: 1.11 to 5.55 MBq (0.03 to 0.15 mCi) per kg of BW.
- Gastroesophageal and pulmonary aspiration studies by oral route (2.1):
  In adults:
- Gastroesophageal studies: 5.55 to 11.1 MBq (0.15 to 0.30 mCi);
- Pulmonary aspiration studies: 11.1 to 18.5 MBq (0.30 to 0.50 mCi).
  In pediatric patients:
- 3.7 to 11.1 MBq (0.10 to 0.30 mCi).

DOSAGE FORMS AND STRENGTHS

The Kit for the Preparation of Technetium Tc 99m Sulfur Colloid Injection is supplied as a package that contains 5 kits. Each kit contains three vials: one 10 mL multi-dose Reaction Vial, a Solution A vial and a Solution B vial. The vials contain the sterile non-pyrogenic, non-radioactive ingredients necessary to produce Technetium Tc 99m Sulfur Colloid Injection (3).

CONTRAINDICATIONS

None (4)

WARNINGS AND PRECAUTIONS

Anaphylactic reactions including rare fatalities have occurred following intravenously administered Technetium Tc 99m Sulfur Colloid. Have resuscitation equipment and personnel immediately available (5.1).

ADVERSE REACTIONS

The most frequently reported adverse reactions include rash, urticaria, anaphylactic shock, and hypotension. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Sun Pharmaceutical Industries, Inc. at 1-800-221-7554 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

USE IN SPECIFIC POPULATIONS

Lactation: Advise a lactating woman to pump and discard breast milk for 24 hours and minimize close contact with infants for 6 hours after receiving a Technetium Tc 99m Sulfur Colloid Injection (8.2).

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 3/2020

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Technetium Tc 99m Sulfur Colloid Injection is indicated:

In adults, to assist in the:

- localization of lymph nodes draining a primary tumor in patients with breast cancer or malignant melanoma when used with a hand-held gamma counter.
- evaluation of peritoneo-venous (LeVeen) shunt patency.

In adults and pediatric patients, for imaging:

- areas of functioning reticuloendothelial cells in the liver, spleen and bone marrow.
- studies of esophageal transit and, gastroesophageal reflux, and detection of pulmonary aspiration of gastric contents.

2 DOSAGE AND ADMINISTRATION

Technetium Tc 99m Sulfur Colloid Injection emits radiation. Use procedures to minimize radiation exposure. Measure patient dose by a suitable radioactivity calibration system immediately before administration.

2.1 Recommended Doses

- Breast cancer or malignant melanoma setting in adults: 3.7 to 37 MBq (0.1 to 1 mCi) in volumes ranging from 0.1 to 1 mL by subcutaneous injection.
- Peritoneo-venous (LeVeen) shunt setting in adults: 37 to 111 MBq (1 to 3 mCi) by intraperitoneal injection, or 12 to 37 MBq (0.3 to 1 mCi) in a volume not to exceed 0.5 mL by percutaneous transtubal (efferent limb) injection. Patient repositioning or other measures may be used to help assure uniform mixing of the radiopharmaceutical with peritoneal fluid.
- Imaging areas of functioning reticuloendothelial cells:
  In adults:

  1. liver/spleen imaging: 37 to 296 MBq (1 to 8 mCi) by intravenous injection;
  2. bone marrow imaging: 111 to 444 MBq (3 to 12 mCi) by intravenous injection.

  In pediatric patients:

  3. liver/spleen imaging in children: 0.56 to 2.78 MBq (0.015 to 0.075 mCi) per kg of body weight (BW) by intravenous injection;
  4. liver/spleen imaging in newborns: 7.4 to 18.5 MBq (0.20 to 0.50 mCi) by intravenous injection;
  5. bone marrow imaging: 1.11 to 5.55 MBq (0.03 to 0.15 mCi) per kg of BW by intravenous injection.

- Gastroesophageal and pulmonary aspiration imaging studies:
  In adults:

6. gastroesophageal studies: 5.55 to 11.1 MBq (0.15 to 0.30 mCi) by oral administration;
7. pulmonary aspiration studies: 11.1 to 18.5 MBq (0.30 to 0.50 mCi) by oral administration.

In pediatric patients:

8. gastroesophageal and pulmonary aspiration studies: 3.7 to 11.1 MBq (0.10 to 0.30 mCi) by oral or nasogastric tube administration. For oral administration, combine the radiopharmaceutical with a milk feeding. For nasogastric tube administration, administer the radiopharmaceutical into the stomach then instill a normal volume of dextrose or milk feeding.

2.2 Drug Preparation and Administration

- The contents of the two Solution vials, the Solution A vial containing the appropriate acidic solution and the Solution B vial containing the appropriate buffer solution, are intended only for use in the preparation of the Technetium Tc 99m Sulfur Colloid Injection and are not to be directly administered to the patient.
- Do not use Sodium Pertechnetate Tc 99m containing oxidants to reconstitute this kit.
- The contents of the kit are not radioactive. However, after the Sodium Pertechnetate Tc 99m is added, maintain adequate shielding of the final preparation. Wear waterproof gloves during the preparation procedure.
- Do not use Sodium Pertechnetate Tc 99m containing more than 10 micrograms per mL of aluminum ion because a flocculent precipitate may occur and such a precipitate may localize in the lung.
- The contents of the kit are sterile and non-pyrogenic. This preparation contains no bacteriostatic preservative. Follow the directions carefully and adhere strictly to aseptic procedures during preparation.

Prepare Technetium Tc 99m Sulfur Colloid Injection by the following aseptic procedure:

1. Remove the dark brown plastic cap from the Sulfur Colloid multi-dose Reaction Vial and swab the top of the vial closure with alcohol to sterilize the surface. Complete the radiation label and affix to the vial. Place the vial in an appropriate lead-capped radiation shield labeled and identified.
2. With a sterile shielded syringe, aseptically obtain 1 to 3 mL of a suitable, oxidant-free sterile and non-pyrogenic Sodium Pertechnetate Tc 99m, each milliliter containing a maximum activity of 18,500 MBq (500 mCi).
3. Aseptically add the Sodium Pertechnetate Tc 99m to the vial.
4. Place a lead cover on the vial shield and dissolve the reagent by gentle swirling.
5. Just before use, remove the red cap from the Solution A vial and swab the top of the vial closure with alcohol to sterilize the surface. Using a sterile needle and syringe, aseptically withdraw 1.5 mL Solution A from the vial. Aseptically Inject 1.5mL Solution A into the multi-dose Reaction Vial and swirl again.
6. Transfer the multi-dose Reaction Vial from vial shield and place in a vigorously boiling water bath (water bath should be shielded with 1/8” to 1/4” lead) deep enough to cover the entire liquid contents of the vial. Keep the vial in the water bath for five minutes.
7. Remove the multi-dose Reaction Vial from the water bath and place in the lead shield and allow to cool for three minutes. Swab the vial closure again with an antiseptic.
8. Just before use, remove the blue cap from the Solution B vial and swab the top of the vial closure with alcohol to sterilize the surface. Using a sterile needle and syringe, aseptically withdraw 1.5 mL Solution B from the vial. Aseptically Inject 1.5 mL Solution B into the multi-dose Reaction Vial and swirl again.

9. Record time and date of preparation.
10. Allow the preparation to cool to body temperature before use. Maintain adequate shielding of the radioactive colloid preparation at all times.
11. Where appropriate, dilute the preparation with sterile Sodium Chloride Injection to bring the dosage to within the recommended range.
12. Mix the multi-dose Reaction Vial and aseptically withdraw material with a sterile shielded syringe for use within 6 hours of preparation. For optimum results this time should be minimized. The vial contains no bacteriostatic preservative. Store the reconstituted vial at 20 to 25°C (68 to77°F). Discard vial 6 hours after reconstitution.
13. Carefully agitate the shielded syringe immediately prior to administration of sulfur colloid to avoid particles aggregation and non-uniform distribution of radioactivity.

Measure the patient dose by a suitable radioactivity calibration system immediately before administration. Check radiochemical purity before patient administration.

Inspect Technetium Tc 99m Sulfur Colloid Injection visually for particulate matter and discoloration before administration, whenever solution and container permit. Do not administer the drug if it contains particulate matter or discoloration; dispose of these unacceptable or unused preparations in a safe manner, in compliance with applicable regulations.

2.3 Radiation Dosimetry

- **Subcutaneous injection to assist in lymph node localization**

Table 1. Estimated Adult Absorbed Radiation Doses from Subcutaneous Administration of Technetium Tc 99m Sulfur Colloid Injection (mSv/MBq and rem/mCi)[1]

Target Organ	mSv/MBq	rem/mCi
Injection Site	9.51	35. 2
Lymph Nodes	0.951	3.52
Liver	0.0028	0.0104
Spleen	0.0017	0.00629
Bone Marrow	0.0019	0.00703
Testes	0.0009	0.0033
Ovaries	0.00018	0.00066
Total Body	0.004	0.0148

[1]Bergqvist L, Strand S-E, Persson B, et al. Dosimetry in Lymphoscintigraphy of Tc 99m Antimony Sulfide Colloid, J Nucl Med, 23: 698-705, 1982.

- **Intravenous Injection**

Adult Radiation Doses

Table 2. Estimated Adult Absorbed Radiation Doses from Technetium Tc 99m Sulfur Colloid Injection Administration (mSv/MBq and rem/mCi)[2]

			Diffuse Parenchymal Disease			
Target Organ	Normal Liver		Early to Intermediate		Intermediate to Advanced	
	mSv/MBq	rem/mCi	mSv/MBq	rem/mCi	mSv/MBq	rem/mCi
Liver	0.091	0.338	0.058	0.213	0.044	0.163

Spleen	0.058	0.213	0.074	0.275	0.115	0.425
Bone Marrow	0.008	0.028	0.012	0.045	0.021	0.079
Testes	0.0003	0.001	0.0005	0.002	0.0008	0.003
Ovaries	0.0016	0.006	0.0022	0.008	0.0032	0.012
Total Body	0.005	0.019	0.005	0.019	0.005	0.018

[2]Modified from Summary of Current Radiation Dose Estimates to Humans with Various Liver Conditions from 99m Tc-Sulfur Colloid, MIRD Dose Estimate Report No 3, J Nucl Med 16: 108A - 108B, 197

Pediatric Radiation Doses

Table 3A. Estimated Pediatric Absorbed Radiation Doses from Technetium Tc 99m Sulfur Colloid Injection Administration of 1 MBq and 1 mCi for Liver/Spleen and Bone Marrow Imaging (in mSv/MBq and rem/mCi)[3]

Age Body Weight		Newborn 3.5 kg	1 year 12.1 kg	5 years 20.3 kg	10 years 33.5 kg	15 years 55 kg
Absorbed Dose						
Target Organ						
Liver	mSv/MBq	0.86	0.38	0.22	0.18	0.13
	rem/mCi	3.2	1.4	0.82	0.67	0.49
Spleen	mSv/MBq	0.76	0.32	0.18	0.13	0.09
	rem/mCi	2.8	1.2	0.65	0.49	0.33
Red Marrow	mSv/MBq	0.16	0.05	0.03	0.022	0.01
	rem/mCi	0.58	0.18	0.11	0.081	0.036
Ovaries	mSv/MBq	0.04	0.02	0.0103	0.0043	0.0022
	rem/mCi	0.14	0.064	0.038	0.016	0.008
Testes	mSv/MBq	0.011	0.006	0.004	0.004	0.001
	rem/mCi	0.04	0.021	0.013	0.014	0.002
Total Body	mSv/MBq	0.032	0.026	0.018	0.012	0.006
	rem/mCi	0.12	0.096	0.066	0.043	0.022

[3]from Age-dependent “S” values of Henrichs et al, Berlin 1982, except for the 1-year old. The 1-year old “S” values were taken from phantom work of the Metabolism and Dosimetry Group at ORNL

Table 3B. Estimated Pediatric Maximum Absorbed Radiation Doses from Administration of the Maximum Recommended Dose for Technetium Tc 99m Sulfur Colloid Injection (mSv and rem) [3]

Age Body Weight		Newborn 3.5 kg		1 year 12.1 kg		5 years 20.3 kg		10 years 33.5 kg		15 years 55 kg	
Maximum Recommended Dose:		a*	b*	a*	b*	a*	b*	a*	b*	a*	b*
MBq		18.5	22.2	33.3	67.3	55.5	114.7	92.5	186.1	151.7	307.1
mCi		0.5	0.6	0.9	1.82	1.5	3.1	2.5	5.03	4.1	8.3
Maximum Absorbed Dose from Maximum Recommended Dose Administered (mSv and rem)											
Target Organ											
Liver	mSv	16	19.2	12.6	25.46	12.3	25.42	16.7	33.6	20.1	40.69

	rem	1.6	1.92	1.26	2.55	1.23	2.54	1.67	3.36	2.01	4.07
Spleen	mSv	14	16.8	10.8	21.83	9.75	20.15	12.2	24.55	13.5	27.33
	rem	1.4	1.68	1.08	2.18	0.98	2.02	1.22	2.45	1.35	2.73
Red Marrow	mSv	2.9	3.48	1.62	3.27	1.65	3.41	2.03	4.08	1.48	3
	rem	0.29	0.35	0.16	0.33	0.17	0.34	0.2	0.41	0.15	0.3
Ovaries	mSv	0.7	0.84	0.58	1.17	0.57	1.18	0.4	0.8	0.34	0.69
	rem	0.07	0.084	0.058	0.117	0.057	0.118	0.04	0.08	0.034	0.069
Testes	mSv	0.2	0.24	0.19	0.38	0.2	0.41	0.35	0.7	0.09	0.18
	rem	0.02	0.024	0.019	0.038	0.02	0.041	0.035	0.07	0.009	0.018
Total Body	mSv	0.6	0.72	0.86	1.74	0.99	2.05	1.07	2.15	0.9	1.82
	rem	0.06	0.072	0.086	0.174	0.099	0.205	0.107	0.215	0.09	0.182

*[a] liver/spleen imaging

*[b] bone marrow imaging

[3] from Age-dependent "S" values of Henrichs et al., Berlin 1982, except for the 1-year old. The 1-year old "S" values were taken from phantom work of the Metabolism and Dosimetry Group at ORNL

- **Oral Administration**

Table 4. Adult Radiation Absorbed Dose from Oral Administration of 1mCi of Technetium Tc99m Sulfur Colloid Injection (mSv/MBq and rem/mCi)

Target Organ	Assumed Residence Time (hr.)	mSv/MBq	rem/mCi
Stomach Wall	1.5	0.038	0.14
Small Intestine	4	0.07	0.26
Upper Large Intestine Wall	13	0.13	0.48
Upper Large Intestine Wall	24	0.089	0.33
Ovaries	-	0.026	0.096
Testes	-	0.001	0.005
Total Body	-	0.005	0.018

- **Intraperitoneal Injection**

Table 5. Adult Absorbed Radiation Dose from Intraperitoneal Injection of 3 mCi of Technetium Tc 99m Sulfur Colloid (mSv/MBq and rem/mCi)

Target Organ	Shunt Open		Shunt Closed	
	mSv/MBq	rem/mCi	mSv/MBq	rem/mCi
Liver	0.092	0.34	0.015	0.056
Ovaries and Testes	0.0003 to 0.0016	0.0012 to 0.006	0.015	0.056
Organs in the Peritoneal Cavity	-	-	0.015	0.056
Total Body	0.0049	0.0180	0.005	0.019

Assumptions: Calculations for the absorbed radiation dose are based upon an effective half-time of 3 hours for the open shunt and 6.02 hours for the closed shunt and an even distribution of the radiopharmaceutical in the peritoneal cavity with no biological clearance.

- **Other Exposure Estimates**

Table 6. Radiation Doses to Hospital Personnel (µSv/MBq and mrem/mCi)

Technician	Preparation of Drug*		Administered Drug	
Target	µSv/MBq	mrem/mCi	µSv/MBq	mrem/mCi
Extremity Dose	0.016	0.0575	0.07	0.25
Whole Body Dose	0.0007	0.0025	0.003	0.0125

*Using shielded vial and syringe

2.4 Imaging Considerations

Breast cancer or malignant melanoma setting in adults:

- In clinical studies, patients received injection of Technetium Tc 99m Sulfur Colloid Injection and a concomitant blue dye tracer in order to enhance the ability to detect lymph nodes. Visual inspection was performed to identify the blue-labeled nodes and a hand held gamma counter was used to identify nodes concentrating the radiopharmaceutical. Multiple methods were used to detect the concentrated radioactivity within lymph nodes. For example, investigators used thresholds of background radioactivity to localize nodes containing a minimum of radioactive counts 3 times higher than the background or containing at least 10 fold higher counts than contiguous nodes.
- In clinical studies of patients with malignant melanoma, preoperative lymphoscintigraphy was usually performed using planar imaging techniques to establish a road map of nodal basins and to facilitate intraoperative identification of lymph nodes. *[see Clinical Studies (14)]*
- Technetium Tc 99m Sulfur Colloid Injection and other tracers may not localize all lymph nodes and the tracers may differ in their extent of lymph node localization. The lymph node localization of Technetium Tc 99m Sulfur Colloid Injection is dependent upon the underlying patency and structure of the lymphatic system, the extent of functional reticuloendothelial cells within lymph nodes and the radiopharmaceutical injection technique. Distortion of the underlying lymphatic system architecture and function by prior surgery, radiation or extensive metastatic disease may result in failure of the radiopharmaceutical and other tracers to localize lymph nodes. The use of Technetium Tc 99m Sulfur Colloid Injection is intended to supplement palpation, visual inspection and other procedures important to lymph node localization. *[see Clinical Studies (14)]*.

  Peritoneo-venous (LeVeen) shunt setting in adults: Following administration of Technetium Tc 99m Sulfur Colloid Injection into the peritoneal cavity, 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. Following transfer into the systemic circulation, the radiopharmaceutical concentrates within the liver (a target organ). Obtain serial images of both the shunt and liver. An adequate evaluation of the difference between total blockage of the shunt and partial blockage may not be feasible in all cases. Transperitoneal absorption of sulfur colloid into the systemic circulation may occur, but it occurs slowly. Therefore, the most definitive scintigraphic evaluation of shunt patency will generally be obtained if there is visualization of both the shunt itself and the liver and/or spleen within the first three hours post intraperitoneal injection of the radiopharmaceutical.

  Imaging areas of functioning reticuloendothelial cells in liver, spleen or bone marrow: Altered biodistribution with lung and soft tissue uptake instead of reticuloendothelial system has been reported after intravenous injection. The size and physical-chemical properties of the sulfur colloid particles formed from the components of the kit may determine the biodistribution of the colloid and its uptake by the reticuloendothelial system. Diseases affecting the reticuloendothelial

system may also alter the expected uptake pattern.

Gastroesophageal and pulmonary aspiration imaging studies: To facilitate the imaging of gastroesophageal reflux consider administering Sulfur Colloid by nasogastric tube.

3 DOSAGE FORMS AND STRENGTHS

Kit for the Preparation of Technetium Tc 99m Sulfur Colloid Injection is supplied in a package that contains 5 kits. All components of a kit are sterile and non-pyrogenic. Each 10mL multi-dose Reaction Vial contains, in lyophilized form, 2 mg sodium thiosulfate anhydrous, 2.3 mg edetate disodium and 18.1 mg bovine gelatin; each Solution A vial contains 1.8 mL 0.148 N hydrochloric acid solution and each Solution B vial contains 1.8 mL aqueous solution of 24.6 mg/mL sodium biphosphate anhydrous and 7.9 mg/mL sodium hydroxide. Included in each 5-kit package are one package insert and 10 radiation labels.

4 CONTRAINDICATIONS

None

5 WARNINGS AND PRECAUTIONS

5.1 Anaphylactic Reactions

Anaphylactic reactions with bronchospasm, hypotension, urticaria and rare fatalities have occurred following intravenously administered Technetium Tc 99m Sulfur Colloid Injection. Have emergency resuscitation equipment and personnel immediately available.

5.2 Radiation Risks

Radiation-emitting products, including Technetium Tc 99m Sulfur Colloid Injection, may increase the risk for cancer, especially in pediatric patients. Use the smallest dose necessary for imaging and ensure safe handling to protect the patient and health care worker. *[see Dosage and Administration (2.3)]*.

5.3 Altered Distribution, Accumulation of Tracer in the Lungs

Technetium Tc 99m Sulfur Colloid Injection is physically unstable, and the particles will settle with time or with exposure to polyvalent cations. These larger particles are likely to be trapped by the pulmonary capillary bed following intravenous injection and result in non-uniform distribution of radioactivity. Agitate the vial adequately before administration of sulfur colloid to avoid particle aggregation and non-uniform distribution of radioactivity. Discard unused drug after 6 hours from the time of formulation. *[see Dosage and Administration (2.2)]*

6 ADVERSE REACTIONS

The most frequently reported adverse reactions, across all categories of use and routes of administration, include rash, allergic reaction, urticaria, anaphylaxis/anaphylactic shock, and hypotension. Less frequently reported adverse reactions are fatal cardiopulmonary arrest, seizures, dyspnea, bronchospasm, abdominal pain, flushing, nausea, vomiting, itching, fever, chills, perspiration, numbness, and dizziness. Local injection site reactions, including burning, blanching, erythema, sclerosis, swelling, eschar, and scarring, have also been reported.

7 DRUG INTERACTIONS

Specific drug-drug interactions have not been studied.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Limited available data with Technetium Tc 99m Sulfur Colloid Injection use in pregnant women have not identified a drug-associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes; technetium Tc 99m crosses the placenta *(see Data)*. Animal reproduction studies have not been conducted with Technetium Tc 99m Sulfur Colloid Injection. All radiopharmaceuticals, including Technetium Tc 99m Sulfur Colloid Injection, have a potential to cause fetal harm depending on the stage of fetal development and the magnitude of the radiopharmaceutical dose. If considering Technetium Tc 99m Sulfur Colloid Injection administration to a pregnant woman, inform the patient about the potential for adverse pregnancy outcomes based on the radiation dose from the drug and the gestational timing of exposure.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2–4% and 15–20%, respectively.

Data

Human Data

Among 14 infants born to pregnant patients exposed to Technetium Tc 99m Sulfur Colloid Injection for lymph node localization, no birth defects were reported following drug exposure.

8.2 Lactation

Risk Summary

Technetium Tc 99m is excreted in human milk during lactation. Exposure of Technetium Tc 99m Sulfur Colloid Injection to a breastfed 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 Technetium Tc 99m Sulfur Colloid Injection and any potential adverse effects on the breastfed child from Technetium Tc 99m Sulfur Colloid Injection or 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 for 24 hours after administration of Technetium Tc 99m Sulfur Colloid Injection. Following higher dose procedures [greater than 370 MBq (10 mCi)], patients should minimize close contact with infants for 6 hours after receiving a Technetium Tc 99m Sulfur Colloid Injection.

8.4 Pediatric Use

The safety and efficacy of Technetium Tc 99m Sulfur Colloid kit in pediatric patients has been shown for the following indications: liver, spleen, and bone marrow imaging, and gastroesophageal and pulmonary aspiration studies.

8.5 Geriatric Use

Clinical studies of Kit for the Preparation of Technetium Tc 99m Sulfur Colloid Injection did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

10 OVERDOSAGE

The clinical consequences of overdosing with Technetium Tc 99m Sulfur Colloid Injection are not known.

11 DESCRIPTION

Kit for the Preparation of Technetium Tc 99m Sulfur Colloid Injection contains a multi-dose Reaction Vial, a Solution A vial and a Solution B vial which contain the sterile non-pyrogenic, non-radioactive ingredients necessary to produce Technetium Tc 99m Sulfur Colloid Injection for diagnostic use by subcutaneous, intraperitoneal, or intravenous injection or by oral administration.

Each 10 mL multi-dose Reaction Vial contains, in lyophilized form 2 mg sodium thiosulfate anhydrous, 2.3 mg edetate disodium and 18.1 mg bovine gelatin; a Solution A vial contains 1.8 mL of 0.148 N hydrochloric acid solution and a Solution B vial contains 1.8 mL aqueous solution of 24.6 mg/mL sodium biphosphate anhydrous and 7.9 mg/mL sodium hydroxide.

When a solution of sterile and non-pyrogenic Sodium Pertechnetate Tc 99m Injection in isotonic saline is mixed with these components, following the instructions provided with the kit, Technetium Tc 99m Sulfur Colloid Injection is formed. The product is intended for subcutaneous, intraperitoneal, or intravenous injection or for oral administration. The precise structure of Technetium Tc 99m Sulfur Colloid Injection is not known at this time.

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 studies is listed in Table 7.

Table 7. Principal Radiation Emission Data[4]

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

[4] Kocher DC: Radioactive decay data tables. DOE/TIC-11026: 108, 1981

11.2 External Radiation

The specific gamma ray constant for Tc 99m is 0.78 R/millicurie-hr at 1cm. The first half-value layer is 0.017 cm of lead (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 8. For example, the use of a 0.25 cm thickness of Pb will attenuate the radiation emitted by a factor of about 1,000.

Table 8. 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 9.

Table 9. Physical Decay Chart: Tc 99m, half-life 6.02 hours

Hours	Fraction Remaining	Hours	Fraction Remaining

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

*Calibration time

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Technetium Tc 99m decays by isomeric transition, emitting a photon that can be detected for imaging purposes. *[see Description (11.1)]*

Following subcutaneous injection, Technetium Tc 99m Sulfur Colloid enters the lymphatic capillaries and is transported with lymph to lymph nodes. However, when there is massive nodal metastatic involvement, the normal transport to lymph nodes is lost because few normal cells remain in the node. *[see Dosage and Administration (2.4)]*

Following intraperitoneal injection, Technetium Tc 99m Sulfur Colloid mixes with the peritoneal fluid; rate of clearance from the cavity allows assessment of the patency of the shunt. Clearance 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.

Following intravenous injection, Technetium Tc 99m Sulfur Colloid is taken up by the reticuloendothelial system (RES), allowing RES rich structures to be imaged.

With oral administration, Technetium Tc 99m Sulfur Colloid is not absorbed accounting for its function in esophageal transit studies, gastroesophageal reflux scintigraphy, and for the detection of pulmonary aspiration of gastric contents.

12.3 Pharmacokinetics

Following intravenous administration, Technetium Tc 99m Sulfur Colloid Injection is rapidly cleared from the blood by the reticuloendothelial system with a nominal half-life of approximately 2 1/2 minutes. Uptake of the radioactive colloid by organs of the RES is dependent upon both their relative blood flow rates and the functional capacity of the phagocytic cells. In the average patient 80 to 90% of the injected collodial particles are phagocytized by the Kupffer cells of the liver, 5 to 10% by the spleen and the balance by the bone marrow.

Following oral ingestion, Technetium Tc 99m Sulfur Colloid is distributed primarily through the gastrointestinal tract with elimination primarily through the feces.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Animal studies to evaluate the carcinogenicity, mutagenesis, or reproductive toxicity potentials of Technetium Tc 99m Sulfur Colloid have not been conducted.

14 CLINICAL STUDIES

14.1 Tracer Localization to Lymph Nodes in Breast Cancer

A systematic review of 43 publications examined procedures that used the injection of Technetium Tc 99m Sulfur Colloid Injection and a blue dye (tracers) to assist surgeons in the localization of lymph nodes among patients with a primary breast cancer lesion. From these publications, 15 studies were identified for inclusion within a meta-analysis, based upon the following criteria: prospective design, minimum number of 50 lymph node localization procedures, and paired outcome data available for both Technetium Tc 99m Sulfur Colloid Injection and blue dye. Within these studies, the number of procedures ranged from 62 to 6,197; in general one procedure involved a single patient but in some uncommon situations, one patient underwent more than one procedure. The patients received subcutaneous Technetium Tc 99m Sulfur Colloid Injection doses ranging between 0.1 and 2 mCi. The mean age of patients ranged from 52 to 60 years, and almost all were female. Lymph nodes that contained radioactivity were generally localized based upon increased counts, in comparison to a background threshold (e.g., nodes containing a minimum of radioactive counts 3 times higher than background or containing at least 10 fold higher counts than contiguous nodes). Radioactivity was measured using a handheld gamma counter.

Table 10 shows the tracer localization rates where the tracer localization rate (%) is defined as the percentage of procedures which had at least one lymph node containing the specific tracer. Random effect meta-analytic measures were used for estimating various rates of tracer localization by procedure along with the respective confidence intervals. The random effect meta-analytical methods take into account the sample size of each study as well as within and between study variability. In general, most procedures involved the resection of lymph nodes in which a tracer had localized to at least one node. However, in some procedures (estimated at approximately 3.4%) neither tracer was localized to a resected lymph node. The reports were insufficient to establish the basis for failed tracer localization. [*see Dosage and Administration (2.4)]*

Table 10 . Tracer Localization by Procedure – Breast Cancer*

Number of Clinical Studies	Number of Procedures	BD Present (%)	SCI Present (%)	Only BD Present (%)	Only SCI Present (%)	Neither SCI nor BD Present (%)
15	9,213	85.1	94.1	3.8	12.1	3.4
95% Confidence Intervals**		81.4, 88.2	91.4, 96.0	2.8, 5.2	9.9, 15.0	2.1, 5.4

BD = blue dye, SCI = Technetium Tc 99m Sulfur Colloid Injection

* Percentage of procedures in which at least one lymph node contained the specific tracer; the percents do not add to 100% due to rounding.

** 95% Confidence Intervals are based on meta-analysis and represent the spread in the individual estimates.

In some of the publications, different methods of Technetium Tc 99m Sulfur Colloid Injection administration were compared: intradermal (ID), subareolar (SA) and intraparenchymal (IP) methods. Generally, more favorable results were seen using the ID and SA routes, with less favorable results reported when surgeons used the IP method.

14.2 Tracer Localization to Lymph Nodes in Malignant Melanoma

A systematic review of eight publications examined the use of Technetium Tc 99m Sulfur Colloid and a blue dye (tracers) to assist surgeons in the localization of lymph nodes among patients with malignant melanoma. A meta-analysis was performed using data from the studies that reported the resected lymph node content of Technetium Tc 99m Sulfur Colloid Injection and blue dye. Four of the eight publications met this criterion and were included in the meta-analysis. Within these four studies, the

number of reported patients ranged from 12 to 94. The patients received subcutaneous Technetium Tc 99m Sulfur Colloid Injection doses ranging between 0.25 to 2 mCi. The patients were aged 15 to 89 years and most (53 to 70%) were male.

Lymph nodes that contained radioactivity were generally localized based upon increased counts, in comparison to a background threshold (e.g., nodes containing a minimum of radioactive counts 3 times higher than background). Radioactivity was measured using a handheld gamma counter.

Table 11 shows the tracer localization rates where the tracer localization rate (%) is defined as the percentage of patients who had at least one lymph node containing the specific tracer. Random effect meta-analytic measures were used for estimating the various rates of tracer localization by patient along with the respective confidence intervals. The random effect meta-analytical methods take into account the sample size of each study as well as within and between study variability. In general, most patients had resected lymph nodes that contained at least one of the tracers. However, in some patients (estimated at approximately 1.6%) neither tracer was localized to a resected lymph node. The reports were insufficient to establish the basis for failed tracer localization. *[see Dosage and Administration (2.4)]*.

Table 11 . Tracer Localization by Patient – Malignant Melanoma*

Number of Clinical Studies	Number of Patients	BD Present (%)	SCI Present (%)	Only BD Present (%)	Only SCI Present (%)	Neither SCI nor BD Present (%)
4	249	83.6	96.4	3.2	15.5	1.6
95% Confidence Intervals**		73.4, 90.4	92.0, 98.5	1.4, 6.9	9.6, 24.1	0.4, 6.5

BD = blue dye, SCI = Technetium Tc 99m Sulfur Colloid Injection

* Percentage of patients in which at least one lymph node contained the specific tracer; the percents do not add to 100% due to rounding.

** 95% Confidence Intervals are based on meta-analysis and represent the spread in the individual estimates.

15 REFERENCES

- Bergqvist L, Strand S-E, Persson B, et al. Dosimetry in Lymphoscintigraphy of Tc 99m Antimony Sulfide Colloid, J Nucl Med., 23: 698-705, 1982.
- Summary of Current Radiation Dose Estimates to Humans with Various Liver Conditions from 99m Tc-Sulfur Colloid, MIRD Dose Estimate Report No 3, J Nucl Med., 16: 108A - 108B, 1975
- Henrichs et al. Estimation of age-dependent internal dose from radiopharmaceuticals, Phys. Med. Biol., 27: 775-784, 1982.
- Kocher DC: Radioactive decay data tables. DOE/TIC-11026: 108, 1981.

16 HOW SUPPLIED/STORAGE AND HANDLING

Kit for the Preparation of Technetium Tc 99m Sulfur Colloid Injection is supplied in a package that contains 5 kits. All kit components are sterile and non-pyrogenic. Each 10mL multi-dose Reaction Vial contains, in lyophilized form, 2 mg sodium thiosulfate anhydrous, 2.3 mg edetate disodium and 18.1 mg bovine gelatin; each Solution A vial contains 1.8 mL 0.148 N hydrochloric acid solution and each Solution B vial contains 1.8 mL aqueous solution of 24.6 mg/mL sodium biphosphate anhydrous and 7.9 mg/mL sodium hydroxide. Included in each 5-kit package are one package insert and 10 radiation labels.

Store the kit at 20-25°C (68-77°F) as packaged and after reconstitution.

This reagent kit for preparation of a radiopharmaceutical is approved for use by persons licensed pursuant to Section 120.547, Code of Massachusetts Regulation 105, or under equivalent license to the U.S. Nuclear Regulatory Commission or an Agreement State.

NDC #45567-0030-1

17 PATIENT COUNSELING INFORMATION

Inform patients they may experience a burning sensation at the injection site.

Inform lactating woman to pump and discard breast milk for 24 hours after administration of Technetium Tc 99m Sulfur Colloid Injection and minimize close contact with infants for 6 hours after receiving a Technetium Tc 99m Sulfur Colloid Injection (8.2).

Manufactured By:

Sun Pharmaceutical Industries, Inc.

29 Dunham Road

Billerica, MA 01821

1-800-221-7554

(for International dial: 1-781-275-7120)

PL-000001

Rev 2.0

Mar 2020

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL - VIAL CONTAINER (PART 1 - 10mL multi-dose Reaction Vial)

NDC 045567-0030-1

STERILE DIAGNOSTIC MULTIDOSE NON-PYROGENIC

Multi-Dose Reaction Vial

for use in the Preparation of Technetium Tc 99m Sulfur Colloid Injection.

Each 10 mL reaction vial contains in lyophilized form 2.0 mg sodium thiosulfate anhydrous, 2.3 mg edetate disodium and 18.1 mg bovine gelatin. Usual Dosage: See complete prescribing information.

Manufactured by:

Sun Pharmaceutical Industries, Inc.

Billerica, MA 01821

PL-000004

Rev 0.3

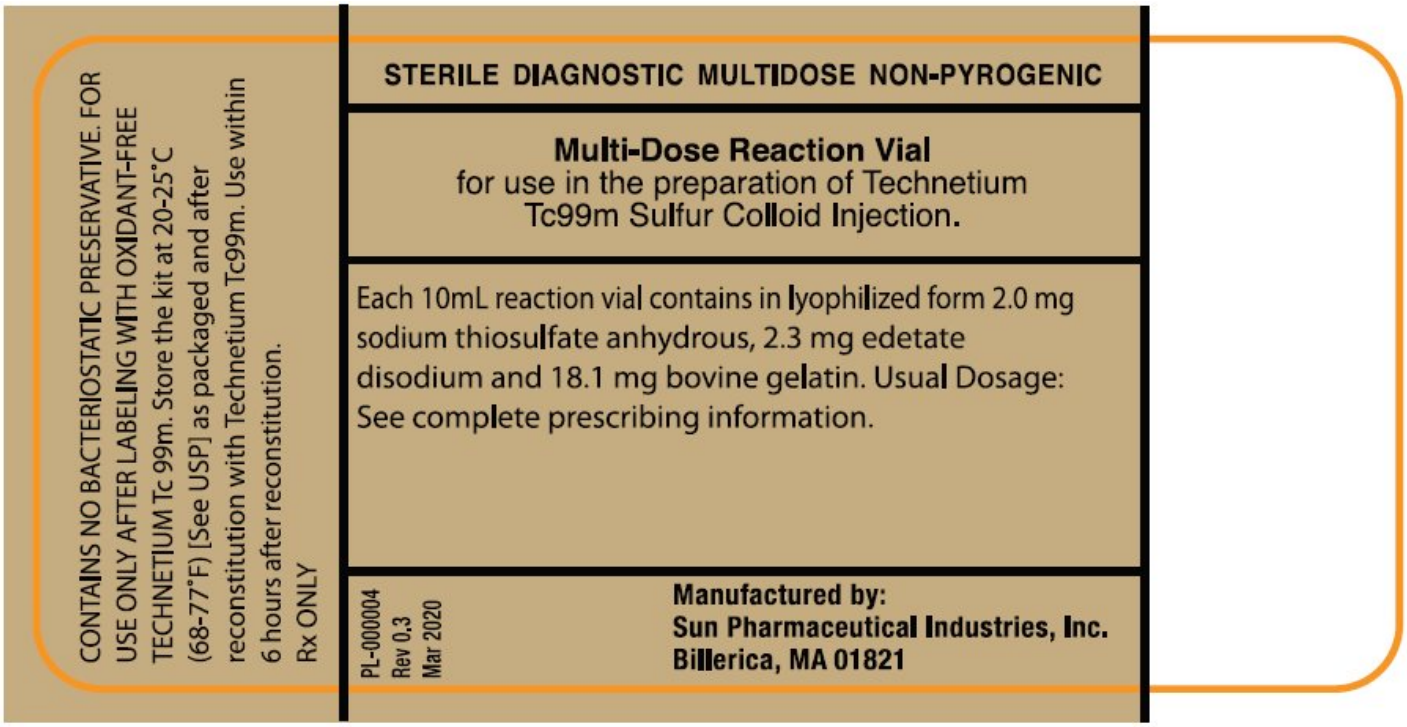
Mar 2020

CONTAINS NO BACTERIOSTATIC PRESERVATIVE FOR
USE ONLY AFTER LABELING WITH OCIDANT-FREE
TECHENTIUM Tc 99m. Store the kit at 20-25°C

(68-77°F) [See USP] as packaged and after reconstitution with Technetium Tc 99m.

Use within 6 hours after reconstitution.

Rx ONLY



PACKAGE/LABEL - PRINCIPAL DISPLAY PANEL - VIAL CONTAINER (PART 2 - 3mL Solution A Vial)

NDC 045567-0030-1

A

Solution A vial contains 1.8mL sterile, non pyrogenic 0.148 N hydrochloric acid solution.

To be used only with the Sulfur Colloid Multi-dose Reaction Vial.

Single Use Vial-Discard Unused Portion

NOT FOR DIRECT INTRAVENOUS INJECTION.

R_X ONLY. STORE AT 20-25°C (68-77°F) [See USP]

Manufactured By: Sun Pharmaceutical Industries, Inc. Billerica, MA 01821

PL-000002

Rev 0.2

Mar 2020

PACKAGE/LABEL - PRINCIPAL DISPALY PANEL - VIAL CONTAINER (PART 3 - 3mL Solution B Vial)

NDC 045567-0030-1

B

Solution B vial contains 1.8mL sterile, non pyrogenic aqueous solution of 24.6 mg/mL sodium biphosphate anhydrous and 7.9 mg/mL sodium hydroxide. To be used only with the Sulfur Colloid Multi-dose Reaction Vial.

Single Use Vial-Discard Unused Portion.

NOT FOR DIRECT INTRAVENOUS INJECTION.

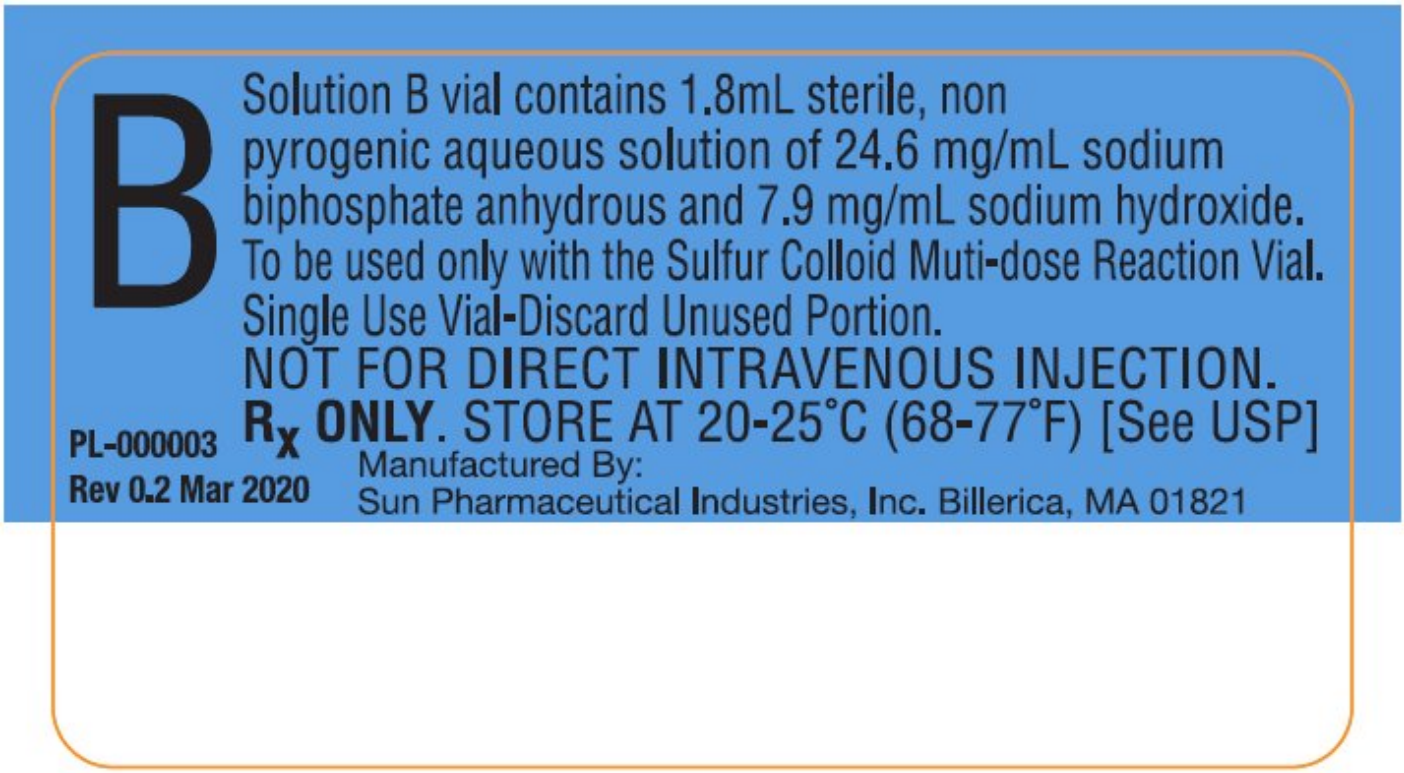
R_X ONLY. STORE AT 20-25°C (68-77°F) [See USP]

Manufactured By: Sun Pharmaceutical Industries, Inc. Billerica MA 01821

PL-000003

Rev 0.2

Mar 2020



PACKAGE/LABEL - PRINCIPAL DISPLAY PANEL - RADIATION LABEL

CAUTION RADIOACTIVE MATERIAL

STERILE, NON-PYROGENIC, DIAGNOSTIC MULTIDOSE TECHNETIUM Tc 99m SULFUR COLLOID

Subcutaneous, Intravenous, Oral, and Intraperitoneal Use

Total MBq (mCi)_____Volume_____

Assay_____MBq/mL(mCi/mL) as of _____

The 10 mL vial contents are made with 2 mg sodium thiosulfate anhydrous, 2.3 mg edetate disodium, 18.1 mg bovine gelatin, the added 1.5 mL of 0.148 N hydrochloric acid solution and the added 1.5 mL aqueous solution of 36.9 mg sodium biphosphate anhydrous and 11.9 mg sodium hydroxide. Contains no bacteriostatic preservative. For use only after labeling with oxidant-free Technetium Tc 99m. Store reconstituted vial at 20-25°C (68-77°F) [See USP]. Use within 6 hours after labeling with Technetium Tc 99m. Usual Dosage: See complete prescribing information. (SEE ENCLOSED PACKAGE INSERT) R_x only

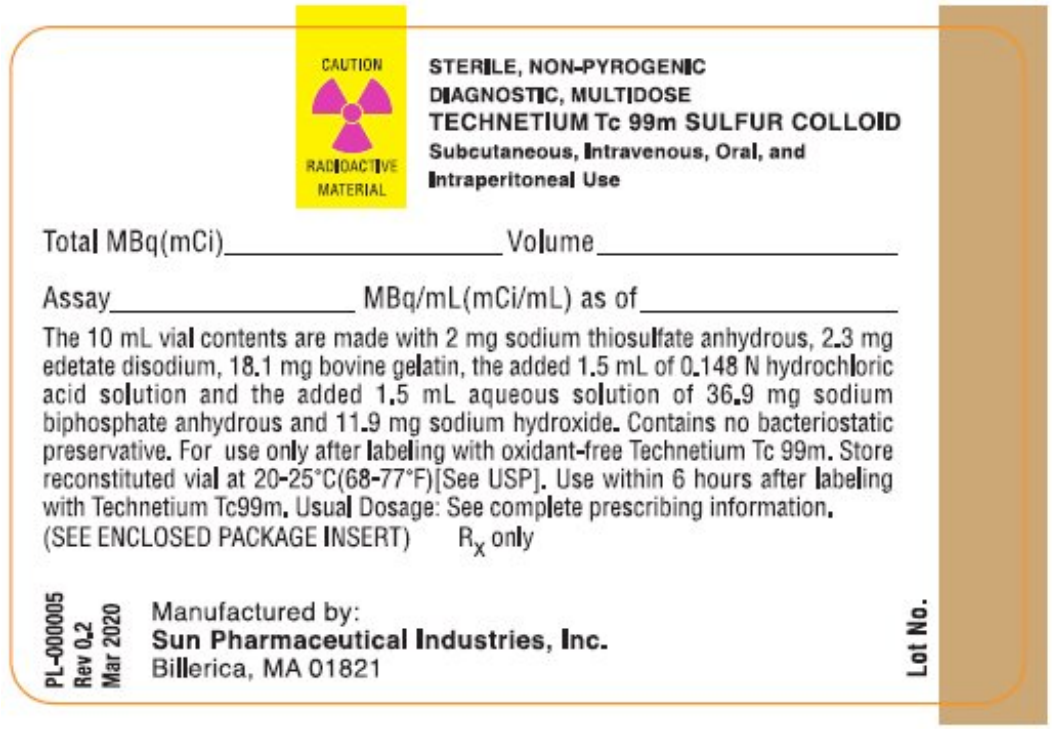
Manufactured by:

Sun Pharmaceutical Industries, Inc. Billerica, MA 01821

PL-000005

Rev 0.2

Mar 2020



PACKAGE/LABEL - PRINCIPAL DISPLAY PANEL - 5 VIAL BOX

NDC 045567-0030-1

Kit for the Preparation of Technetium Tc99m Sulfur Colloid Injection

CAUTION: Federal (U.S.A.) law prohibits dispensing without prescription

Rx only.

Manufactured By:

Sun Pharmaceutical Industries, Inc. Billerica, MA 01821

For Customer Service call: 1-800-221-7554

Sterile Diagnostic Multidose Non-Pyrogenic

CONTENTS: 1 package insert, 10 radiation labels, 5 multi-dose reaction vials, 5 Solution A vials and 5 Solution B vials. Each 10 mL multi-dose reaction vial contains 2 mg sodium thiosulfate anhydrous, 2.3 mg edetate disodium and 18.1 mg bovine gelatin. Each Solution A vial contains 1.8 mL 0.148 N hydrochloric acid. Each solution B vial contains 1.8 mL aqueous solution of 24.6 mg/mL sodium biphosphate anhydrous and 7.9 mg/mL sodium hydroxide. Contains no bacteriostatic preservative. For intravenous use only after labeling with oxidant-free Technetium Tc 99m.

Store the kit at 20-25°C (68-77°F) [See USP] as packaged and after reconstitution

Use within 6 hours after labeling with Technetium Tc 99m.

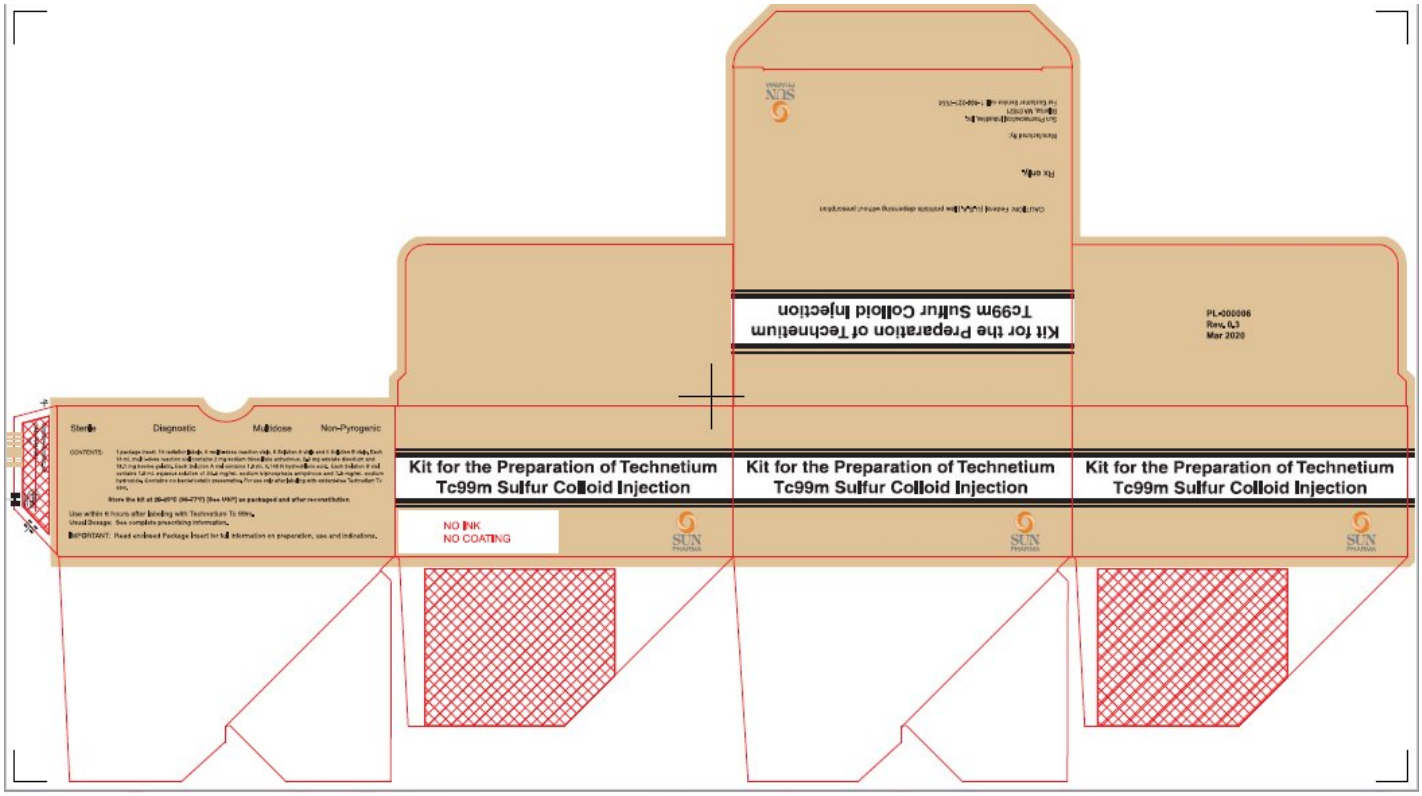
Usual Dosage: See complete prescribing information.

IMPORTANT: Read enclosed Package Insert for full information on preparation, use and indications.

PL-000006

Rev 0.3

Mar 2020



KIT FOR THE PREPARTION OF TECHNETIUM TC99M SULFUR COLLOID

technetium tc 99m sulfur colloid kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:45567-0030

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45567-0030-1	1 in 1 PACKAGE; Type 0: Not a Combination Product	04/19/1978	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 VIAL	10 mL
Part 2	1 VIAL	3 mL
Part 3	1 VIAL	3 mL

Part 1 of 3

KIT FOR THE PREPARTION OF TECHNETIUM TC99M SULFUR COLLOID

reaction vial injection, powder, lyophilized, for solution

Product Information

Route of Administration	INTRAVENOUS, ORAL, SUBCUTANEOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TECHNETIUM TC-99M SULFUR COLLOID (UNII: 556Q0P6PB1) (TECHNETIUM TC-99M SULFUR COLLOID - UNII:556Q0P6PB1)	GELATIN, UNSPECIFIED	18.1 mg in 10 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM THIOSULFATE ANHYDROUS (UNII: L0IYT1O31N)	2.0 mg in 10 mL
EDETATE DISODIUM (UNII: 7FLD91C86K)	2.3 mg in 10 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		10 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA017858	04/19/1978	

Part 2 of 3

KIT FOR THE PREPARTION OF TECHNETIUM TC99M SULFUR COLLOID

solution a solution

Product Information

Route of Administration	INTRAVENOUS, ORAL, SUBCUTANEOUS

Inactive Ingredients

Ingredient Name	Strength
HYDROCHLORIC ACID (UNII: QTT17582CB)	0.148 mol in 3 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		3 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA017858	04/19/1978	

Part 3 of 3

KIT FOR THE PREPARTION OF TECHNETIUM TC99M SULFUR COLLOID

solution b solution

Product Information

Route of Administration	INTRAVENOUS, ORAL, SUBCUTANEOUS

Inactive Ingredients

Ingredient Name	Strength
SODIUM HYDROXIDE (UNII: 55X04QC32I)	7.9 mg in 3 mL
SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS (UNII: KH7I04HPUU)	24.6 mg in 3 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		3 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA017858	04/19/1978	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA017858	04/19/1978	

Labeler - Sun Pharmaceutical Industries, Inc. (139261648)

Registrant - Sun Pharmaceutical Industries, Inc. (139261648)

Establishment

Name	Address	ID/FEI	Business Operations
Sun Pharmaceutical Industries, Inc.		139261648	ANALYSIS(45567-0030) , LABEL(45567-0030) , PACK(45567-0030) , MANUFACTURE(45567-0030)