SESTAMIBI - sestamibi injection, powder, lyophilized, for solution
AnazaoHealth Corporation

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Sestamibi
(for the preparation of Tc99m Sestamibi injection)

Dear Medical Professional,

Per your order, we have compounded Sestamibi as a sterile, freeze-dried preparation in a 10 mL vial. The characteristics of this preparation are described below.

DESCRIPTION

AnazaoHealth's compounded Sestamibi vial is a sterile, non-pyrogenic preparation that consists of a lyophilized mixture of 1.5mg of Copper (1) tetrafluoroborate, 3.9 mg of Sodium Citrate Dihydrate, 1.5 mg of L-Cysteine HCL Monohydrate, 30 mg Mannitol and 0.112 mg of Tin Chloride. It is maintained under an inert nitrogen atmosphere. Prior to lyophilization the pH is 5.3 to 5.9. The pH of the final reconstituted product is 5.5 to 6.0. It contains no antimicrobrial preservative.

CLINICAL PHARMACOLOGY

When Sestamibi is reconstituted with Tc99m pertechnetate, a complex of Tc99m Sestamibi is formed and is the active ingredient of the reconstituted product. When administered intravenously, Tc99m Sestamibi shows rapid myocardial uptake and its distribution follows a linear relationship with coronary blood flow.

Tc99m Sestamibi is a lipophilic agent that is taken up by the mitochondria of myocardial cells by passive diffusion and appears to accumulate in viable myocardial tissue.

INDICATIONS AND USAGE

Sestamibi is a diagnostic agent used to assess areas of reversible myocardial ischemia in the presence or absence of infracted myocardium. Evaluation of myocardial ischemia can be accomplished with rest and cardiovascular stress techniques.

PREPARATION

Instructions for the preparation of Tc99m Sestamibi

1. Inspect vial to ensure there are no cracks in the glass.
2. Reconstitute with 1- 3ml of non-pyrogenic, oxidant free Sodium Pertechnetate Tc99m injection.
3. Remove equal amount of inert gas from vial and shake vigorously 10 times.
4. Place vial in a boiling water bath for 10 minutes beginning when the bath begins boiling again.
5. Do not allow water to come in contact with aluminum crimp.

1. Remove vial from water bath place in lead shield and allow to cool for 15 minutes
2. Behind appropriate shielding visually inspect the contents of the vial. Contents should be clear and free of particulate matter.
3. pH of the final reconstituted product is 5.5 to 6.0.

4. This vial contains no preservatives - contents should be used within **6 hours.**
5. Store shielded vial at 15-25 degrees Celsius until use and withdraw dose aseptically.

Instructions for the determination of radiochemical purity in Tc99m Sestamibi

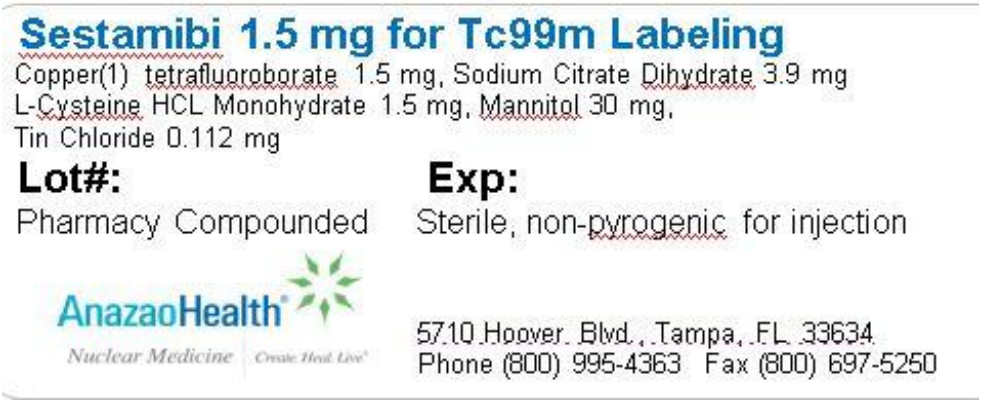
1. Dry a pre-cut 2.5cm X 7.5cm Baker-Flex Aluminum Oxide coated, plastic TLC #1 B-F Plate at 100 degrees Celsius for 1 hour and store in a desiccator. Remove strip just prior to use.
2. Apply one drop of Ethanol using a 1ml syringe with a 22-26guage needle 1.5cm from the bottom of the plate. Do not allow to dry.
3. Put two drops of Tc99m Sestamibi side by side on top to the Ethanol then return plate to desiccator and allow to dry (typically 15 minutes).
4. Prepare the TLC take by pouring Ethanol to a depth of 3-4 cm then cover the tank and let equilibrate for 10 minutes.
5. Develop the plate in the covered TLC tank, in Ethanol, for a distance of 5cm from the point of application.
6. Cut the TLC plate 4cm from the bottom and measure the Tc99m activity in each piece with appropriate radiation detector.
7. Calculate the % Tc99m Sestamibi as:
   Activity top piece (front)/ Activity both pieces (origin + front) x 100

Storage and Handling

This preparation is recommended to be stored in the refrigerator prior to reconstitution..

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Figure 1



SESTAMIBI

sestamibi injection, powder, lyophilized, for solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:51808-208
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
TETRAKIS(2-METHOXYISOBUTYLISOCYANIDE)COPPER(I) TETRAFLUOROBORATE (UNII: N6OU7HJ70P) (TETRAKIS(2-METHOXYISOBUTYLISOCYANIDE)COPPER(I) TETRAFLUOROBORATE - UNII:N6OU7HJ70P)	TETRAKIS(2-METHOXYISOBUTYLISOCYANIDE)COPPER(I) TETRAFLUOROBORATE	1.5 mg

Inactive Ingredients	
Ingredient Name	**Strength**
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	3.9 mg
CYSTEINE HYDROCHLORIDE (UNII: ZT934N0X4W)	1.5 mg
MANNITOL (UNII: 3OWL53L36A)	30 mg
STANNOUS CHLORIDE (UNII: 1BQV3749L5)	0.112 mg

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:51808-208-01	1 in 1 KIT		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		05/23/2012	

Labeler - AnazaoHealth Corporation (011038762)

Establishment

Name	Address	ID/FEI	Business Operations
AnazaoHealth Corporation		011038762	MANUFACTURE(51808-208)

Revised: 5/2012 AnazaoHealth Corporation