TETROFOSMIN - tetrofosmin 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.

Tetrofosmin
(for the preparation of Tc99m Tetrofosmin injection)

Dear Medical Professional,

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

DESCRIPTION

AnazaoHealth's compounded Tetrofosmin vial is a sterile, non-pyrogenic preparation that consists of a lyophilized mixture of 0.35 mg of Tetrofosmin, 1.5 mg of D-Gluconate, 0.03 mg of Stannous Chloride Dihydrate, 0.48 mg of Disodium Sulphosalicylate, and 2.7 mg of Sodium Hydrogen Carbonate and is maintained under an inert nitrogen atmosphere. It contains no antimicrobrial preservative.

INDICATIONS

Tetrofosmin is a diagnostic agent used to assess areas of reversible myocardial ischemia in the presence or absence of infracted myocardium and is also used to assess ventricular function.

PHYSICAL HALF-LIFE & TARGET ORGANS

The physical half-life of technetium, Tc99m, is 6 hours and has a principal radiation emission of gamma photons with a mean energy of 140 KeV.

Estimated Absorbed Radiation Dose (Technetium Tc99m Tetrofosmin Injection)

	Absorbed radiation dose			
	Exercise		Rest	
Target organ	rad/mCi	µGy/MBq	rad/mCi	µGy/MBq
Gall bladder wall	0.123	33.2	0.180	48.6
Upper large intestine	0.075	20.1	0.113	30.4
Bladder wall	0.058	15.6	0.071	19.3
Lower large intestine	0.057	15.3	0.082	22.2
Small intestine	0.045	12.1	0.063	17.0
Kidney	0.039	10.4	0.046	12.5
Salivary glands	0.030	8.04	0.043	11.6
Ovaries	0.029	7.88	0.035	9.55
Uterus	0.027	7.34	0.031	8.36
Bone surface	0.023	6.23	0.021	5.58
Pancreas	0.019	5.00	0.018	4.98
Stomach	0.017	4.60	0.017	4.63
Thyroid	0.016	4.34	0.022	5.83
Adrenals	0.016	4.32	0.015	4.11
Heart wall	0.015	4.14	0.015	3.93

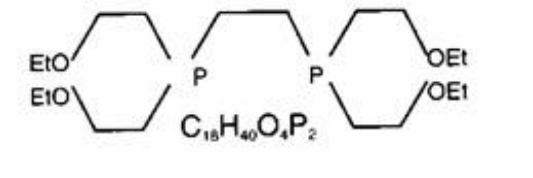
Red marrow	0.015	4.14	0.015	3.97
Spleen	0.015	4.12	0.014	3.82
Muscle	0.013	3.52	0.012	3.32
Testes	0.013	3.41	0.011	3.05
Liver	0.012	3.22	0.015	4.15
Thymus	0.012	3.11	0.009	2.54
Brain	0.010	2.72	0.008	2.15
Lungs	0.008	2.27	0.008	2.08
Skin	0.008	2.22	0.007	1.91
Breasts	0.008	2.22	0.007	1.83

Dose calculations were performed using the standard MIRD method (MIRD Pamphlet No.1 (rev),Society of Nuclear Medicine, 1976).

Effective dose equivalents (EDE) were calculated in accordance with ICRP 53 (Ann. ICRP 18 (1-4),1988) and gave values of 8.61 × 10-3 mSV/MBq and 1.12 × 10-2 mSV/MBq after exercise and rest, respectively.

CLINICAL PHARMACOLOGY

The structural formula for tetrofosmin is:



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

Tc99m Tetrofosmin 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.

CONTRAINDICATIONS

There are no known contraindications for this preparation.

DOSE AND ROUTE OF ADMINISTRATION

Depending on the protocol for rest/stress imaging, doses of 10 to 30 mCi (370 to 1110 MBq) are given intravenously

PREPARATION

1. Snap off the plastic lid and place in appropriate lead shielding. Wipe the septum with 70% isopropyl alcohol and allow it to dry.
2. Using a 10 mL syringe, dilute up to 360 mCi of Tc99m with saline and add to vial. The total volume should be between 6 mL -12 mL and the Tc99m concentration should not exceed 30 mCi/mL (360 mCi/12 mL).
3. After adding the Tc99m, insert a 0.22 µm filtered vent needle and, using a separate syringe,

withdraw 3 mL of gas from the vial, allowing sterile filtered air into the vial. Remove vent needle and syringe.
4. Mix gently and invert several times for 10 seconds.
5. **Let stand for 15 minutes at room temperature as the complexes form.**
6. Inspect vial through a lead glass shield for particulate matter. Do not use if the solution is not clear.
7. Store at 2°- 8°C (36°- 46°F) and **use within 12 hours after mixing**. Radiochemical purity should be at least 90% prior to administration
8. QC info: Solvent – Ethyl Acetate, Strip – Whatman CHR% Tag = top counts/total counts X 100%

STORAGE

The preparation should be stored in the refrigerator at 2- 8(C (36 - 46(F) and protected from light.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

TETROFOSMIN

tetrofosmin injection, powder, lyophilized, for solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:51808-223
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
TETROFOSMIN (UNII: 3J0KPB596Q) (TETROFOSMIN - UNII:3J0KPB596Q)	TETROFOSMIN	0.35 mg

Inactive Ingredients	
Ingredient Name	**Strength**
DISODIUM SULFOSALICYLATE (UNII: WFP6MAA96R)	0.48 mg
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	2.7 mg
GLUCONIC ACID (UNII: R4R8J0Q44B)	1.5 mg

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51808-223-02	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

Revised: 5/2012 AnazaoHealth Corporation