PYROPHOSPHATE - pyrophosphate 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.

Stannous Pyrophosphate

Dear Medical Professional,

Per your order, we have compounded Stannous-Pyrophosphate as a sterile lyophilized powder. The characteristics of this preparation are:

DESCRIPTION

AnazaoHealth compounds Stannous-Pyrophosphate as a sterile lyophilized powder for the preparation of Tc99m Pyrophosphate. Each 10 ml reaction vial contains: 27.6 milligrams sodium pyrophosphate decahydrate, 3.5 milligrams stannous chloride, all lyophilized under an atmosphere of nitrogen. Prior to lyophilization the pH is adjusted with hydrochloric acid. The pH of the reconstituted drug is between 4.5 and 7.5. No bacteriostatic preservative is present

INDICATIONS AND USAGE

Stannous Pyrophosphate is indicated as a blood pool imaging agent which may be used for gated pool imaging and for the detection of sites of gastrointestinal bleeding. When administered intravenously, 15-30 minutes prior to intravenous administration of sodium pertechnetate Tc99m for in vivo red blood cell labeling, approximately 75 percent of the injected activity remains in the blood pool. The modified in vivo/in vitro red blood cell labeling method may also be used for blood pool imaging.

It is also indicated as a skeletal imaging agent used to demonstrate areas of altered osteogenesis, and a cardiac imaging agent used as an adjunct in the diagnosis of acute myocardial infarction.

DOSAGE AND ADMINISTRATION

The recommended adult dose of Tc99m Pyrophosphate Injection is:

- 5 to 15 mCi for skeletal imaging
- 10 to 15 mCi for cardiac imaging
- one-third (0.33) to the entire vial contents, followed 15 to 20 mCi of sodium pertechnetate Tc 99m, for blood pool imaging

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Figure 1

PYROPHOSPHATE

pyrophosphate injection, powder, lyophilized, for solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:51808-218
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM PYROPHOSPHATE (UNII: O352864B8Z) (PYROPHOSPHORIC ACID - UNII:4E862E7GRQ)	SODIUM PYROPHOSPHATE	27.6 mg

Inactive Ingredients	
Ingredient Name	**Strength**
STANNOUS CHLORIDE (UNII: 1BQV3749L5)	3.5 mg

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:51808-218-01	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(51808-218)

Revised: 5/2012 AnazaoHealth Corporation