DEXTRAN 75 - dextran 75 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.

Dextran 75

Dear Medical Professional,

Per your order, we have compounded Dextran 75 as a lyophilized powder for injection. The characteristics of this preparation are as follows:

DESCRIPTION

AnazaoHealth supplies compounded Dextran 75 for the preparation of Tc-99m Dextran 75. Each reaction vial contains 10 mg of Dextran 75, 0.30mg of stannous chloride, 0.73 mg Sodium Citrate and 1 mg of dextrose (lyophilized mixture, under nitrogen atmosphere), per unit dose vial.

Mechanism of Action

Dextran, when labeled with technetium Tc99m and given intravenously, is distributed throughout the body in much the same way as the patient's serum, and serves as a suitable tracer with which to transiently image the vascular compartment

INDICATIONS AND USAGE

Technetium Tc99m Dextran by intravenous administration is indicated as a cardiac blood pool imaging agent and as an adjunct in the diagnosis of pericardial effusion, ventricular aneurysm, or GI Bleed

DOSAGE AND ADMINISTRATION

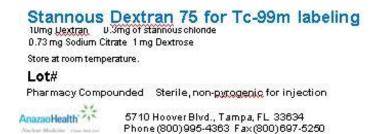
To prepare injection, up to 40 mCi of an oxidant-free sodium pertechnetate Tc 99m solution is aseptically injected into the vial, minimum volume 1ml, mix gently and let Dextran dissolve completely for 10 minutes

Storage and Handling

Injection should be administered within 6 hours after preparation. Before and after reconstitution- Store at room temperature

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Figure 1



DEXTRAN 75

dextran 75 injection, powder, lyophilized, for solution

Product Information

Product Type HUMAN PRESCRIPTION DRUG Item Code (Source) NDC:51808-210

Route of Administration INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTRAN 75 (UNII: JY83SHX053) (DEXTRAN 75 - UNII:JY83SHX053)	DEXTRAN 75	10 mg

Inactive Ingredients Ingredient Name Strength STANNOUS CHLORIDE (UNII: 1BQV3749L5) 0.3 mg ANHYDROUS DEXTROSE (UNII: 5SL0G7R0OK) 1 mg

SODIUM CITRATE (UNII: 1Q73Q2JULR) 0.73 mg

Product Characteristics

Color	Score	no score
Shape	Size	
Flavor	Imprint Code	
Contains		

Packaging

1	r ackaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:51808-210-01	1 in 1 KIT		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		07/01/2012	

Labeler - Anazao Health Corporation (011038762)

Establishment			
Name	Address	ID/FEI	Business Operations
Anazao Health Corporation		011038762	MANUFACTURE(51808-210)

Revised: 7/2012 AnazaoHealth Corporation