GLUCOHEPTONATE - glucoheptonate 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.

Glucoheptonate

Dear Medical Professional,

Per your order, we have compounded Glucoheptonate as a sterile freeze-dried mixture. The characteristics of this preparation are

DESCRIPTION

AnazaoHealth supplies compounded Glucoheptonate for the preparation of Tc 99m Glucoheptonate. Each vial contains 50 mg calcium glucoheptonate and 0.6 mg tin metal as stannous chloride. The vial is back filled with inert gas and may contain a partial vacuum.

CLINICAL PHARMACOLOGY

When injected intravenously, Technetium Tc 99m Glucoheptonate is rapidly cleared from the blood. In patients with normal renal function, less than 15% of the initial activity remains in the blood after one hour. About 40% of the injected dose is excreted in the urine in one hour, while about 70% is excreted in 24 hours. In patients with renal disease, the blood clearance and urinary excretion of the radiopharmaceutical are delayed.

Up to 15% of the injected dose is retained in the kidneys. The renal retention is greater in the cortex than in the medulla. The radiopharmaceutical may be bound to the proximal convoluted tubules, which are located primarily in the renal cortex.

Technetium Tc 99m Glucoheptonate tends to accumulate in intracranial lesions that are associated with excessive neovascularity or an altered blood-brain barrier. The drug does not accumulate in the choroid plexus or salivary glands.

INDICATIONS AND USAGE

Tc 99m Glucoheptonate may be used to image the kidney and brain and to assess renal and brain perfusion.

PREPARATION

Preparation of Technetium Tc 99m Glucoheptonate is done by the following aseptic procedure:

1. Waterproof gloves should be worn during the preparation procedure.
2. Snap off the plastic lid and place room temperature reaction vial in an appropriate lead shield.
3. Swab the rubber closure of the vial with a germicide.
4. Inject 1 - 5 ml sterile, additive free sodium pertechnetate Tc 99m injection containing up to 5,920 MBq (160 mCi) into the vial. Be sure to maintain inert atmosphere in vial by introducing as little air as possible during reconstitution. NOTE: If sodium pertechnetate Tc 99m injection must be diluted, use only preservative free Sodium Chloride Injection USP.
5. Secure the lead shield cover. Swirl the vial gently to mix contents and let stand 3 to 5 minutes prior to use.
6. Record the date and time of preparation on a pressure-sensitive label.

7. Affix pressure-sensitive label to shield.
8. Examine vial contents; if the solution is not clear and free of particulate matter and/or discoloration on visual inspection, it should not be used.
9. Measure the radioactivity by suitable calibration system and record prior to patient administration.
10. Appropriate quality control is recommended.
11. Injection should be administered within 12 hours of preparation.

Storage and Handling

This preparation should be stored at room temperature before and after reconstitution.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Figure 1

GLUCOHEPTONATE

glucoheptonate injection, powder, lyophilized, for solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:51808-213
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CALCIUM GLUCEPTATE (UNII: L11651398J) (CALCIUM GLUCEPTATE - UNII:L11651398J)	CALCIUM GLUCEPTATE	50 mg

Inactive Ingredients	
Ingredient Name	**Strength**
STANNOUS CHLORIDE (UNII: 1BQV3749L5)	0.6 mg

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:51808-213-01	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(51808-213)

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