MEBROFENIN - mebrofenin 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.

Mebrofenin

Dear Medical Professional,

Per your order, we have compounded Mebrofenin as a sterile solution. The characteristics of this preparation are

DESCRIPTION

AnazaoHealth supplies compounded Mebrofenin for the preparation of Tc-99m Mebrofenin. Each reaction vial contains 10 mg Mebrofenin and 0.2 mg tin as stannous chloride. The vial is back filled with nitrogen gas after lyophilization. The vial may contain a partial vacuum.

INDICATIONS AND USAGE

Technetium Tc-99m Mebrofenin by intravenous administration is indicated as a hepatic imaging agent, used in the diagnosis of liver disease

DOSAGE AND ADMINISTRATION

The suggested intravenous dose range of Technetium Tc 99m Mebrofenin in the average patient (70 kg) is:

Nonjaundiced patient: 74 - 185 MBq (2-5 mCi)

Patient with serum bilirubin level greater than 1.5 mg/dL: 111-370 MBq (3-10 mCi)

The patient should be in a fasting state, 4 hours is preferable. False positives (non-visualization) may result if the gallbladder has been emptied by ingestion of food.

An interval of at least 24 hours should be allowed before repeat examination

PREPARATION

To prepare injection, follow this 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 – 3 ml Sterile additive free sodium pertechnetate Tc-99m injection containing up to 740 MBq (20 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 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. Use within 12 hours of preparation

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Figure 1

MEBROFENIN

mebrofenin injection, powder, lyophilized, for solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:51808-216
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MEBROFENIN (UNII: 7PV0B6ED98) (MEBROFENIN - UNII:7PV0B6ED98)	MEBROFENIN	10 mg

Inactive Ingredients	
Ingredient Name	**Strength**
STANNOUS CHLORIDE (UNII: 1BQV3749L5)	0.2 mg

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:51808-216-01	1 in 1 KIT		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		06/19/2012	

Labeler - AnazaoHealth Corporation (011038762)

Establishment

Name	Address	ID/FEI	Business Operations
AnazaoHealth Corporation		011038762	MANUFACTURE(51808-216)