BICISATE - bicisate 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.

Bicisate (ECD)
(for the preparation of Tc99m Bicisate injection)

Dear Medical Professional,

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

DESCRIPTION

AnazaoHealth supplies ECD as a compounded kit for preparing Tc99m ECD. Each Reaction vial contains 1.35 mg of ECD, 0.54 edetate disodium, 36mg mannitol and 0.125 mg stannous chloride dehydrate. The vial is back filled with inert gas and may contain a partial vacuum.

Each ECD buffer vial contains a total volume of 1 mL that includes 6.15 mg sodium phosphate dibasic and 0.69 mg sodium phosphate monobasic

CLINICAL PHARMACOLOGY

Tc99m Bicisate forms a stable, lipophilic complex that crosses intact cell membranes and blood brain barrier by passive diffusion. The amount of tc99m bicisate is stable in the brain until about 6 hours

INDICATIONS AND USAGE

Tc99m bicisate is indicated as an adjunct to conventional CT or MRI imaging in the localization of stroke in patients in whom stroke has already been diagnosed

HALF-LIFE

The physical half-life for Technetium is 6.02 hours

CONTRAINDICATIONS

There are no known contraindications for this preparation.

DOSAGE AND ADMINISTRATION

The recommended dose for a 70 kg patient is 10-30 mCi

PREPARATION

For best results, use tc99m from a generator eluted within 24 hours. The eluate should be used within 2 hours of elution.

Reconstitution Instructions:

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, draw up 100 mCi of tc99m (in approximately 2 mL) and inject into the ECD Buffer, being sure to withdraw an equal amount of gas from the vial to neutralize pressure.
3. With a sterile syringe, inject 3 mL of 0.9% sodium chloride into the reaction vial to dissolve the contents. Remove an equal volume of air to maintain pressure within the vial. Shake the contents of the vial for a few seconds.
4. With another sterile syringe, immediately (within 30 seconds) withdraw 1 mL out of the reaction vial and inject it into the buffer vial. Discard the reaction vial
5. Swirl the contents of the buffer vial for a few seconds and allow this mixture to stand for 30 minutes at room temperature.
6. Examine the vial contents for particulates and discoloration prior to patient administration. It should be clear of any particulates.

It is recommended that the kit be stored refrigerated until use; at such time the product should be aseptically withdrawn

Storage and Handling

This kit should be stored in the refrigerator prior to reconstitution and the reaction vial protected from light.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Figure 1

BICISATE

bicisate injection, powder, lyophilized, for solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:51808-217
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BICISATE (UNII: 3JXF0Z0XOI) (BICISATE - UNII:3JXF0Z0XOI)	BICISATE	1.35 mg

Inactive Ingredients	
Ingredient Name	**Strength**
EDETATE DISODIUM (UNII: 7FLD91C86K)	0.54 mg

MANNITOL (UNII: 3OWL53L36A)	36 mg
STANNOUS CHLORIDE (UNII: 1BQV3749L5)	0.125 mg

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51808-217-01	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(51808-217)

Revised: 5/2012 AnazaoHealth Corporation