

**EXAMETAZIME HMPAO- exametazime 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.*

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**Exametazime (HMPAO)**  
**(for the preparation of Tc99m Exametazime injection)**

Dear Medical Professional,

Per your order, we have compounded Exametazime as a sterile, freeze-dried preparation in a 10 mL vial. The characteristics of this preparation are described below

**DESCRIPTION**

AnazaoHealth's compounded Exametazime vial is a sterile, non-pyrogenic preparation that consists of a lyophilized mixture of 1 mg of Exametazime, 6.75 mg of Sodium Chloride, 11.4 µg of Stannous Chloride Dihydrate and is maintained under an inert nitrogen atmosphere. The kit also contains a vial of Cobalt Chloride, which contains 0.3 mg of cobalt chloride hexahydrate, or Methylene Blue 1% (methylene blue 10 mg/mL) and Phosphate Buffer (monobasic sodium phosphate, sodium chloride, dibasic sodium phosphate) This kit contains no antimicrobial preservative

**CLINICAL PHARMACOLOGY**

**Cerebral Scintigraphy**

When Exametazime is reconstituted with Tc99m pertechnetate, a lipophilic complex of Tc99m Exametazime is formed and is the active ingredient of the reconstituted product. The lipophilic complex crosses the blood-brain barrier. It converts to the less lipophilic complex 12% per hour. The preparation is good for 30 minutes without the use of a stabilizer. The *in vitro* addition of cobalt chloride helps to stabilize the complex for 6 hours.

**Leukocyte (WBC) Labeling**

The lipophilic complex of Tc99m Exametazime is taken up by leukocytes and selectively retained by neutrophils. Cobalt chloride, as a stabilizer, may be used with this procedure as well

**INDICATIONS AND USAGE**

Exametazime is a diagnostic agent used as an adjunct in the detection of altered cerebral perfusion in stroke patients and is also indicated for white blood cell labeling as an adjunct in the localization of abdominal infections and inflammatory bowel disease

**PHYSICAL HALF-LIFE & TARGET ORGANS**

The physical half-life of technetium, Tc99m, is 6 hours and has a principal radiation emission of gamma photons with a mean energy of 140 KeV.

**CONTRAINDICATIONS**

There are no known contraindications for this preparation.

**DOSAGE AND ADMINISTRATION**

## Cerebral Scintigraphy

The recommended dose range for IV administration is 10 to 20 mCi (370 to 740 MBq).

## Leukocyte (WBC) Labeling

The recommended dose range for IV administration is 7 to 25 mCi (259 to 925 MBq)

## 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 15-80 mCi of tc99m. Dilute this to 7.5 mL with sterile preservative free saline and inject into the vial, being sure to withdraw an equal amount of gas from the vial to neutralize pressure.
  3. Rock and invert the shielded vial for 10 seconds. Wait 2 minutes before adding stabilizer to allow for tagging.
- Add stabilizer to extend the length of time before use
  - If no stabilizer is added, use the vial within 30 minutes.

### Stabilizer Use:

Cobalt Chloride as a stabilizer: Wait 2 minutes after adding tc99m. Then add 3 mL of Cobalt Chloride to tc99m HMPAO. Solution is clear but slightly tan, which is normal. Swirl contents to mix and inspect solution for particulates. Draw 0.1 mL for a quality control sample. Solution is stable for 6 hours. This stabilizer can be used in WBC labeling

Methylene blue and Phosphate buffer as a stabilizer: Add 0.5 mL of 1% methylene blue to 4.5 mL of phosphate buffer solution. Swirl contents to mix then draw 3 mL and add to HMPAO within 2 minutes of mixing tc99m. Filter the final solution using a 0.22µm filter into an empty sterile vial. Draw 0.1 mL sample for quality control. Radiochemical purity must be 80% or higher. Solution is stable for 4 hours. This stabilizer is not recommended for use in WBC labeling

## Storage and Handling

The preparation is recommended to be stored in the refrigerator at 2- 8(C (36 - 46(F)

## PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

### HMPAO (Exametazime) for Tc99m Labeling

Exametazime 1 mg Sodium Chloride 6.75mg

Stannous Chloride Dihydrate 11.4ug

Lot#: Exp:

Pharmacy Compounded Sterile, non-pyrogenic for injection



5710 Hoover Blvd., Tampa, FL 33634  
Phone (800) 995-4363 Fax (800) 697-5250

## EXAMETAZIME HMPAO

exametazime injection, powder, lyophilized, for solution

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:51808-214
<b>Route of Administration</b>	INTRAVENOUS		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
EXAMETAZIME (UNII: G29272NCKL) (EXAMETAZIME - UNII:G29272NCKL)	EXAMETAZIME	1 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
SODIUM CHLORIDE (UNII: 451W47IQ8X)	6.75 mg
STANNOUS CHLORIDE (UNII: 1BQV3749L5)	11.4 ug

**Product Characteristics**

<b>Color</b>		<b>Score</b>	no score
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:51808-214-01	1 in 1 KIT		

**Marketing Information**

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

**Labeler** - AnazaoHealth Corporation (011038762)**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
AnazaoHealth Corporation		011038762	MANUFACTURE(51808-214)