DIMERCAPTOSUCCINIC ACID DMSA- dimercaptosuccinic acid 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.

DMSA (Dimercaptosuccinic acid)

Dear Medical Professional,

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

DESCRIPTION

AnazaoHealth supplies DMSA as a compounded kit for preparing Tc 99m DMSA. Each Reaction vial contains 1.1 mg meso-2, 3-dimercaptosuccinic acid, 0.2 mg tin as stannous chloride, and 0.7 mg ascorbic acid. The vial is back filled with inert gas and may contain a partial vacuum.

Each Acetate buffer vial contains 1.2 ml Sodium Acetate .25 N. pH 5.2 to 5.6.

LDO normal saline included for dilution of prepared kit, if required

CLINICAL PHARMACOLOGY

Technetium Tc 99m DMSA, when administered intravenously apparently binds to plasma proteins in the blood and collects in the renal cortex.

INDICATIONS AND USAGE

Technetium Tc 99m DMSA by intravenous administration is indicated as a static kidney imaging agent.

CONTRAINDICATIONS

There are no known contraindications.

DOSAGE AND ADMINISTRATION

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

1. Waterproof gloves should be worn during the preparation
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 as close to 1 cc as possible of sterile additive free sodium pertechnetate Tc 99m injection containing up to 1480 MBq (40 mCi) into the vial freshly eluded within 2 hours from a technetium generator. 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 Low Dissolved Oxygen (LDO)
5. Secure the lead shield cover. Swirl the vial gently to mix contents and let stand for 15 minutes. Add 1 ml Acetate buffer at this time. (This will interfere with the tagging process if introduced any earlier). Buffer must be added (May be added up to 1 hour after Tc 99m)
6. Examine vial contents; if the solution is not clear and free of particulate matter and discoloration on visual inspection, it should not be used

7. Measure the radioactivity by a suitable calibration system and record prior to patient administration
8. Buffered material should be used within 2 hours
9. Appropriate quality control is recommended

Tagging Tips

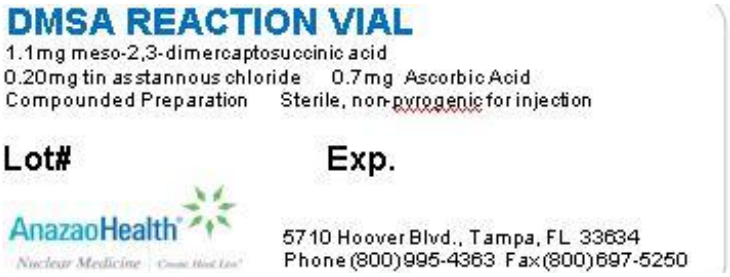
- If you need only a one or two mCi dose for your patient, use about 10 mCi of Tc 99m for your kit. Do not stretch your kit to 40 mCi if you do not need to. We have tested the kits to 40 mCi with a Friday generator eluted on Monday but recommend using only what you need
- Keep your volumes low. Take your Tc 99m and dilute to about 1cc with the Low Dissolved Oxygen saline and inject into the DMSA kit
- Let the kit stand for about 15 minutes with just the Tc 99m and DMSA (NO BUFFER)
- After 15 minutes, then add the buffer. This is only for patient comfort and will interfere with the tagging process if introduced any earlier
- After buffering you can add additional “Low Dissolved Oxygen” saline to dilute the kit
- You should inject the dose within 2 hours after making the kit for best results

Storage and Handling

Store the kit at 2°-8°C (36°-46°F) and protect from light

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Figure 1



DIMERCAPTOSUCCINIC ACID DMSA

dimercaptosuccinic acid injection, powder, lyophilized, for solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:51808-211
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
2,3-DIMERCAPTOSUCCINIC ACID (UNII: 4S9JU7XF01) (2,3-DIMERCAPTOSUCCINIC ACID - UNII:4S9JU7XF01)	2,3-DIMERCAPTOSUCCINIC ACID	1.1 mg

Inactive Ingredients	
Ingredient Name	**Strength**

STANNOUS CHLORIDE (UNII: 1BQV3749L5)	0.20 mg
ASCORBIC ACID (UNII: PQ6CK8PD0R)	0.7 mg

Product Characteristics			
Color		**Score**	no score
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51808-211-01	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 - AnazaoHealth Corporation (011038762)

Establishment

Name	Address	ID/FEI	Business Operations
AnazaoHealth Corporation		011038762	MANUFACTURE(51808-211)

Revised: 7/2012 AnazaoHealth Corporation