IN-111 DTPA - in-111 dtpa 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.

In-111 DTPA (In-111 Pentetate Disodium)

DESCRIPTION

In-111 DTPA is supplied as a sterile, pyrogen-free, isotonic, aqueous solution that is buffered to pH 7 to 8. At calibration time, each milliliter contains 2.5 mCi of Pentetate Indium Disodium In-111 (no carrier-added) and sodium bicarbonate for pH adjustment.

CHARACTERISTICS

Indium 111 decays by electron capture with a physical half-life of 67.9 hour. The energies of the photons that are useful for detection and imaging studies are:

Radiation Mean % Disintegration Mean Energy (keV)

Gamma-2 90.2 171.3

Gamma-3 94.0 245.4

INDICATIONS AND USAGE

In-111 DTPA is indicated for use in radionuclide cisternography

CLINICAL PHARMACOLOGY

After intrathecal administration, the In-111 DTPA is absorbed from the subarachnoid space and the remainder flows superiorly to the basal cisterns within 2 to 4 hours and subsequently will be apparent in the Sylvian cisterns, the interhemispheric cisterns, and over the cerebral convexities. In normal individuals, the it will have ascended to the parasagittal region within 24 hours with simultaneous partial or complete clearance of activity from the basal cisterns and Sylvian regions. In contrast to air, In-111 DTPA does not normally enter the cerebral ventricles

CONTRAINDICATIONS

There are no known contraindications

DOSAGE AND ADMINISTRATION

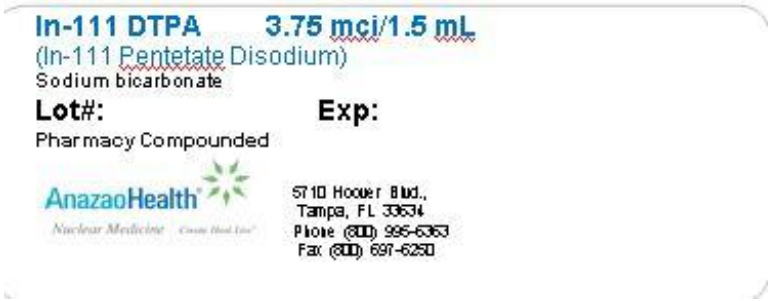
Extreme care must be exercised to assure aseptic conditions in intrathecal injections. The maximum recommended intrathecal dose in the average patient (70kg) is 18.5 megabecquerels (500 microcuries). The patient dose should be measured by a suitable radioactivity calibration system immediately prior to administration. Parenteral drug preparations should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

Storage and Handling

Store vial in its lead shield at a temperature of 5-30º C. Do not freeze

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Figure 1



IN-111 DTPA

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Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:51808-125
Route of Administration	INTRATHECAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
INDIUM IN-111 PENTETATE DISODIUM (UNII: 7UIT3ZGC8E) (PENTETIC ACID - UNII:7A314HQM0I)	INDIUM IN-111 PENTETATE DISODIUM	3.75 mCi in 1.5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:51808-125-01	1.5 mL in 1 VIAL		

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