

JEANATOPE- iodinated i-125 albumin injection, solution
Iso-Tex Diagnostics, Inc.

Jeanatope

R_x Only

DESCRIPTION

Jeanatope 1-125 (Iodinated 1-125 Albumin Injection) is a sterile, nonpyrogenic, aqueous solution for intravenous use. Each milliliter provides approximately 10 mg protein (normal human serum albumin), 1.6 mg sodium phosphate, 16 mg sodium biphosphate, not more than 0.4 mg guanidine hydrochloride, sodium chloride for isotonicity, and 9 mg benzyl alcohol as a preservative. The stabilizer aceryltryptophanate and sodium caprylate have a concentration of less than 0.0089M. The pH has been adjusted to 7.2-7.8 with sodium hydroxide or hydrochloric acid.

Jeanotope I-125 was prepared from the blood that was non-reactive when tested for hepatitis B surface antigen (HBsAg) and HIV antibody.

PHYSICAL CHARACTERISTICS

Iodine 125 decays by electron capture with a physical half-life of 60.14 days.¹ Photons that are useful for detection and imaging studies are listed in Table 1.

TABLE 1
Principal Radiation Emission Data

Radiation	Mean % per Disintegration	Mean Energy (keV)
Gamma-1	6.7	35.0
X-rays	140.0	28.0 ²

¹Dillman LT, Von der Lage FC; Radionuclide Decay Schemes and Nuclear Parameters for Use in Radiation-Dose Estimation. MIRD Pamphlet No. 10, pg. 71 Soc Nucl Med, 1975.

²Weighted mean energy

External Radiation

The specific gamma ray constant for I-125 is 1.5 R/millicurie-hour at 1 cm. The first half-value thickness of Pb for I-125 is .002 mm. A range of values for the relative attenuation of the radiation emitted by this radionuclide that results from interposition of various thicknesses of Pb is shown in Table 2. For example, the use of .02 min of Pb will decrease the external radiation exposure by a factor of 1,000.

TABLE 2

Radiation Attenuation by Lead Shielding	
Shield Thickness (Pb) mm	Attenuation Factor
0.02	0.5
0.06	10 ⁻¹
0.12	10 ⁻²
0.20	10 ⁻³
0.30	10 ⁻⁴
0.40	10 ⁻⁵

To correct for physical decay of this radionuclide, the fractions that remain at selected intervals before and after the time of calibration are shown in Table 3.

TABLE 3

Physical Decay Chart: I-125 half-life 60.14 days					
Days	Fraction Remaining	Days	Fraction Remaining	Days	Fraction Remaining
-14	1.175	1	0.989	18	0.813
-12	1.148	2	0.977	20	0.794
-10	1.122	3	0.966	22	0.776
-8	1.096	4	0.955	25	0.750
-7	1.084	5	0.944	30	0.708
-6	1.072	6	0.933	35	0.668
-5	1.060	7	0.923	40	0.631
-4	1.047	8	0.912	45	0.596
-3	1.035	10	0.891	50	0.562
-2	1.023	12	0.871	55	0.531
-1	1.012	14	0.851	60	0.501
0*	1.000	16	0.831	75	0.422

* Calibration time

CLINICAL PHARMACOLOGY

Following intravenous injection, radioiodinated serum albumin is uniformly distributed throughout the intravascular pool within 10 minutes; extravascular distribution takes place more slowly. Labeled albumin also can be detected in the lymph and in certain body tissues within 10 minutes after injection, but maximum distribution of radioactivity throughout the extravascular space does not occur until two to four days after administration. The time at which extravascular activity is maximal has been designated as the "equilibrium time." When this point has been reached, the radioactivity remaining in the intravascular and extravascular spaces decreases slowly and exponentially in parallel fashion.

The administered radioactivity is eliminated almost entirely in the urine, only about 2 percent of the total dose ultimately appearing in the feces. The biologic half-life of labeled albumin is dependent upon a number of factors, and

published studies have varied considerably in their reporting of this figure. It has ranged, in the literature, from below 10 days to over 20 days. One important factor affecting the biologic half-life is the initial rate of excretion, and this depends in part on the quality of the labeled albumin. With Jeanatope 1-125 the biologic half-life in normal individuals has been reported to be approximately 14 days.

INDICATIONS AND USAGE

Jeanotope I-125 is indicated for use in the determination of total blood and plasma volume.

CONTRAINDICATIONS

At present there are no known contraindications to the use of this preparation.

WARNINGS

Radiopharmaceuticals should not be administered to patients who are pregnant or to nursing mothers unless the expected benefit to be gained outweighs the potential hazards.

Since I-125 is excreted in human milk during lactation, formula-feedings should be substituted for breast-feedings.

Ideally, examinations using radiopharmaceuticals, especially those elective in nature, of a woman of childbearing capability should be performed during the first few (approximately 10) days following the onset of menses.

A few instances of hyperpyrexia and aseptic (chemical) meningeal irritation have been reported with the use of this product in cisternography. This material is not approved for use in cisternography.

PRECAUTIONS

In the use of any radioactive material, care should be taken to insure minimum radiation exposure to the patient and occupational workers consistent with proper patient management.

ADVERSE REACTIONS

Although the immunological properties of serum albumin are believed to be virtually unaltered by the iodinated process, there is a theoretical possibility that allergic reactions may occur in patients receiving additional doses a number of weeks after an initial dose.

DOSAGE AND ADMINISTRATION

Radioiodinated serum albumin is administered intravenously. When a procedure such as a blood volume determination is to be repeated, the total dosage administered in any one week should not exceed 7.4 megabecquerels (200 microcuries).

To minimise the uptake of radioactive iodine by the thyroid, prior administration of Lugol's Solution (Strong Iodine Solution USP) may be used. Ten drops of Lugol's Solution three times a daily, beginning at least 24 hours before administration of Iodinated Serum Albumin I-125 and continuing for one or two weeks thereafter, is a suitable dose.

Complete assay data for each vial are provided on the container.

Note: The expiration date given on the container pertains to the biologic properties of the material and not to the radioactivity label, it is important to make certain that the radioactivity in the dose at the time of administration is sufficient for the intended use.

Visual Inspection

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

Jeanotope (Iodinated I-125 Albumin Injection) may be colorless to very pale yellow. Solutions with excessive coloration should not be used.

The patient dose should be measured by a suitable radioactivity calibration system immediately prior to administration.

Note: A shielded syringe should be used for withdrawing and injecting the Iodinated I-125 Albumin.

Total Blood and Plasma Volumes

Dosage may range from .185 to 1.85 megabecquerels (5 to 50 microcuries).

Blood Volume Determination

A. Preparation of Reference Solution

Remove an aliquot of the contents of the vial to be used in the procedure identical in volume to the dose to be administered to the patient. Prepare a reference solution using normal saline as a diluent. The recommended dilution is 1:4000 (Dilution Factor (DF) = 4000). Determine the radioactivity concentration (net cpm/ml) of the reference solution. Care must be taken to assure that the reference solution and the blood samples (Step B3) are assayed using the same geometric configuration.

A. Administration of Dose

1. Inject the dose into a large vein in patient's arm. Measure the residual radioactivity in the syringe and needle.

2. Destroy the syringe after injecting. Do not attempt to resterilize.

CAUTION: the syringe should be disposed of in accordance with the US Nuclear Regulatory Commission or Agreement State regulations pertaining to the disposal of radioactive waste.

3. At 5 and 15 minutes after injecting the dose, withdraw blood samples **from the patient's other arm** with a sterile heparinized syringe.

B. Calculation of Blood Volume

1. Take a known aliquot from each blood sample and determine radioconcentration in net cpm/mL.

2. Plot the 5- and 15-minute sample counts (net cpm/mL) on semilog graph paper using the average count value of each sample and determine the radioconcentration at injection time (zero time) by drawing a straight line through the 15- and 5- minute points to zero time. The x ordinate of the graph is the sample withdrawal time and the logarithmic y ordinate is radioconcentration in net cpm/mL.

3. Calculate the patient's blood volume (in mL) using the following formula:

$$\frac{\text{Net cpm/mL reference solution}}{\text{Net cpm/mL patient's blood sample}} \times \text{DF} = \text{blood volume (in mL)}$$

Sample Blood Volume Calculations

Volume of blood sample aliquot = 1.0 mL

Volume of reference solution aliquot = 1.0 mL

Net counts at zero time = 2500

Net counts obtained from reference solution aliquot = 2725

$$\text{Using the formula above gives } \frac{2725}{2500} \times 4000 = 4360 \text{ mL}$$

Serial Blood Volume Determinations

Jeanotope (Iodinated I-125 Albumin Injection) is administered in sufficiently low dosage to permit repetitions as often as required by clinical circumstances. It must be remembered that it is always necessary to correct for background radioactivity remaining in the blood from former determinations. Therefore, for each determination after the first one, a background blood sample must be taken just before the iodinated I-125 Albumin is injected.

Background Blood Sample:

1. Prior to injecting Jeanotope I-125, withdraw background blood sample

- from large vein in patient's arm with a sterile heparinized syringe.
2. Leaving needle in a patient's vein, detach syringe containing blood sample.
 3. Withdraw Jeanotop I-125 from the vial and administer (see instructions under **Blood Volume Determination, Administration of Dose**).
 4. Determine radioconcentration in net cpm/mL of aliquots taken from background and postinjection blood samples, and from the reference solution.

The radioconcentration (net cpm/mL) per aliquot of the background blood sample must be subtracted from the radioconcentration per aliquot of the blood sample obtained after the injection of Iodinated I-125 Albumin. The formula for calculating each blood volume determination after the first one thus becomes:

$$\frac{\text{Net cpm/mL reference solution}}{\text{Net cpm/mL postinjection blood sample} \text{ minus } \text{Net cpm/mL background blood sample}} \times 400 = \text{blood volume (in mL)}$$

Plasma Volume Determination

The procedure is essentially the same as that for blood volume determination, except that the blood sample drawn from the patient is centrifuged, the red blood cells are removed, and net cpm/mL of the plasma is determined. The formula for calculation of plasma volume, therefore is:

$$\frac{\text{Net cpm/mL reference solution}}{\text{Net cpm/mL patient's plasma sample}} \times 400 = \text{plasma volume (in mL)}$$

Radiation Dosimetry

The estimated absorbed radiation doses to an average patient (70 kg) from an intravenous injection of 1.85 megabecquerels (50 microcuries) of iodinated I-125 Albumin USP are shown in Table 4.

Tissue	Rads
Blood	.15
Whole-body	.025 - .035

Method of Calculation: Hine GJ, Johnston RE: Absorbed Doses from Radionuclides, J. Nucl Med 11:468-469, 1970.

For doses of 2.775, 5.55, 18.5 and 27.75 megabecquerels (75, 150, 500 and 750 microcuries), the estimated absorbed doses are 1.5, 3, 10 and 15 times the number of rads given respectively.

HOW SUPPLIED

Jeanotope (Iodinated I-125 Albumin Injection USP) is available in multiple dose vials containing the following amounts of activity on the date of calibration: 3.7 megabequerels /10.0 ml (100 microcuries/10.0 ml), 18.5 megabequerels/0.5 ml (500 microcuries/0.5 ml) and 37.0 megabequerels/1.0 ml (1.0 millicuries/1.0 ml). Complete assay data for each vial is provided on the container.

The maximum concentration of Iodinated I-125 Injection does not exceed one millicurie per milliliter at time of calibration.

Storage

Store between 2°C - 8°C.

This radiopharmaceutical is licensed by the Texas Department of Health, Bureau of Radiation Control for distribution to persons licensed pursuant

to 41.26 (b) and Appendix 41-C, Group I and Group II, "Texas Regulations for Control of Radiation," or under equivalent licenses of the U.S.

Nuclear Regulatory Commission, an Agreement State, or a Licensing State.

Iso-Tex Diagnostics, Inc.

P.O. Box 909 . Friendswood, Texas 77549 . USA.

Phone: 281-482-1231 . Customer Service: 800-477-4839 . Fax: 281-482-1070

Packaging

JEANATOPE Cat. No. 7732
IODINATED I-125
NDC 50914-7732-5

Lot No. _____ Total mCi _____
 Activity _____ μ Ci/ml _____
 Volume _____ ml _____
 Total mCi _____
 As of _____ 6 PM/CST _____
 Exp. Date _____

As of _____ 6 PM/CST _____
 Exp. Date _____

NOTE: Each unit of plasma used in the manufacture of Albumin (human) has been tested and found to be non-reactive for Hepatitis B Surface Antigen (HBsAg) and HIV anti-body by FDA-approved tests.

CAUTION: Radioactive Material

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JEANATOPE Cat. No. 7732
IODINATED I-125
NDC 50914-7732-5

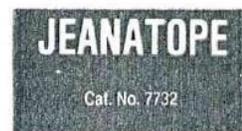
Lot No. _____ Total mCi _____
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CAUTION: Radioactive Material

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IODINATED I-125
Albumin Injection USP

For intravenous administration.

See accompanying directions.

Caution: Federal (U.S.A.) law prohibits dispensing without prescription.

Iso-Tex Diagnostics, Inc.
 P.O. Box 909 Friendswood, Tx. 77546

Contains Iodinated I-125 albumin in a sterile aqueous solution. Each milliliter provides approximately 10 mg of protein (albumin human), 16 mg dibasic sodium phosphate, 1.5 mg monobasic sodium phosphate, not more than 0.4 mg guanidine hydrochloride, sodium chloride for isotonicity, and 9 mg benzyl alcohol as a preservative; pH adjusted to 7.2-7.8 with sodium hydroxide or hydrochloric acid.

CAUTION: This drug contains radioactive material which must be handled only by qualified personnel in conformity with United States Nuclear Regulatory Commission or Agreement State (USA) regulations. Care must be taken to avoid excessive exposure to its radiation. Shielding or equivalent radiation protective measures must be used.

JEANATOPE

iodinated i-125 albumin injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:50914-7732
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IODINATED I-125 SERUM ALBUMIN (UNII: 68WQQ3N9TI) (IODINATED I-125 SERUM ALBUMIN - UNII:68WQQ3N9TI)	IODINATED I-125 SERUM ALBUMIN	0.01 mCi in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALBUMIN HUMAN (UNII: ZIF514RVZR)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50914-7732-5	1 in 1 BOX		
1		11 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA017836	06/01/1990	

Labeler - Iso-Tex Diagnostics, Inc. (181202995)**Establishment**

Name	Address	ID/FEI	Business Operations
Iso-Tex Diagnostics, Inc.		181202995	manufacture(50914-7732)

Revised: 4/2014

Iso-Tex Diagnostics, Inc.