Iodinated I 125 Albumin Injection (IHSA I 125)
Rx Only.

Diagnostic-For Intravenous Use

DESCRIPTION
Iodinated I 125 Albumin Injection (IHSA I 125) is supplied in an isotonic solution as a sterile, non-pyrogenic diagnostic radiopharmaceutical for intravenous administration. The amount of free (unbound) iodine at the time of production is 3% or less.

Multiple dose vials containing approximately 3.7 megabecquerels (100 microcuries) Iodinated I 125 Albumin Injection at a specific activity of 37 kilobecquerels (1.0 microcurie) iodine I 125 per milligram of albumin on the calibration date. Each milliliter contains 370 kilobecquerels (10 microcuries) (10 milligrams) Iodinated I 125 Albumin, 9 milligrams sodium chloride, 29 micrograms dibasic sodium phosphate anhydrous and 15 micrograms monobasic potassium phosphate, and 0.7 micrograms of guanidine hydrochloride, with 0.9% (v/v) benzyl alcohol added as a preservative. Sodium hydroxide or hydrochloric acid may be present for pH adjustment.

ACTIONS
The dilution principle is used to determine an unknown volume by introducing a known quantity of radioactive material into that volume and measuring the concentration after adequate mixing.

INDICATIONS AND USAGE
IHSA I 125 (Iodinated I 125 Albumin Injection) is indicated for blood and plasma volume determinations, measurement of circulation time and cardiac output.

CONTRAINDICATIONS
Radiopharmaceuticals are contraindicated in pregnancy and during lactation, and in persons less than 18 years of age, unless in the judgment of the physician the situation requires their use.

Iodinated I 125 Albumin Injection is not to be used intramuscularly.

PRECAUTIONS
To block the possible accumulation of iodine I 125 in the thyroid gland resulting from the catabolism of Iodinated I 125 Albumin, prior administration of Lugol's Solution is recommended. This precaution is particularly important when dosages of more than 1.85 megabecquerels (50 microcuries) are given.

ADVERSE REACTIONS
The possibility of allergic reaction in patients receiving subsequent doses several weeks after the initial one should be borne in mind.

DOSAGE AND ADMINISRATION

Blood and Plasma Volume Determinations
The dosage required is in the range of 0.185 to 1.85 megabecquerels (5 to 50 microcuries), depending on the sensitivity of the detection instrumentation. Doses of less than 740 kilobecquerels (20 microcuries) will suffice with well-type scintillation counters. With such doses, determinations can be safely repeated as often as clinically indicated.

PROCEDURE AND CALCULATIONS FOR MULTIDOSE VIAL
1. A measured quantity of IHSA I 125 is withdrawn from the product vial and administered intravenously to the subject, using sterile technique. The quantity (CPM) administered may be determined by counting the syringe before and after intravenous injection of its contents and calculating the amount injected from the difference in the two counts.

2. A volume of blood is drawn at five and fifteen minutes after injection of albumin, using an appropriate anticoagulant. The net CPM/mL of the two whole blood samples should then be plotted on semilog paper and extrapolated to zero circulation time to obtain the net CPM/mL of whole blood used in the equation in Step 3. This technique will yield optimal accuracy, since removal of albumin starts immediately after injection.

3. For whole blood volume, an exact volume of the blood is counted. Four milliliters is suggested, in order to attain improved counting statistics, and to provide counting geometry comparable to that of the standard.

Whole Blood Volume (mL): V_{WB} =

$$\frac{\text{Net CPM Injected}}{\text{Net CPM per 1 mL of Whole Blood}}$$

4. Plasma volume can be determined by centrifuging part of the same blood sample, and measuring the radioactivity of an exact volume of plasma. The net CPM/mL of the two plasma samples should then be plotted on semilog paper and extrapolated to zero circulation time to obtain the net CPM/mL of plasma used in the equation included in this step. This technique will yield optimal accuracy, since removal of albumin starts immediately after injection.

Plasma Volume (mL): V_P =

$$\frac{\text{NET CPM Injected}}{\text{Net CPM per 1 mL of Plasma}}$$

5. Red cell volume can be calculated by subtracting the plasma volume from the wholeblood volume.

Red Cell Volume (mL): $V_{RC} = V_{WB} - V_P$

NOTE: A comparison of the radioactive hematocrit with the microhematocrit will give an indication of the accuracy of the procedure and calculations.

The standard, blood, and plasma counts must be taken under identical sample volume and geometric conditions relative to the detector crystal or the difference accounted for in the computations by an appropriate correction factor.

Blood Circulation and Cardiac Output
A dose of 370 to 925 kilobecquerels (10 to 25 microcuries) may be used. For the measurement of circulation time, the time is measured for the albumin to move from the site of injection to the point in question. When the first albumin arrives at the site, a very marked increase in counting rate over the site is observed. A directionally shielded detector is needed.

Correction for Radioactive Decay
Each package of IHSA I 125 is carefully assayed and marked with the radioactive strength as of a specified date. In the event that the drug is to be used at a later date, the radioactive strength may be calculated from the following chart. The strength on the indicated date must be multiplied by the factor corresponding to the number of days after the indicated date.

Iodine I 125 Half Life 60.1 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	1.059	7	0.922	40	0.631
-4	1.047	8	0.912	45	0.595
-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	0.832	75	0.421

*Calibration day.

HOW SUPPLIED

Catalog Number

350 IHSA I 125 Injection available in 3.7 megabecquerels (100 microcuries) multiple dose vials with a concentration of approximately 10 microcuries/milliliter.

STORAGE
IHSA I 125 should be stored refrigerated 2-8°C (36-46°F).

The U.S. Nuclear Regulatory Commission has approved distribution of this radiopharmaceutical to persons licensed to use byproduct material listed in Section 35.100, and to persons who hold an equivalent license issued by an Agreement State.

Revised 8/2000
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