

¹²⁵I albumin

Seralb[®], ¹²⁵I HSA, iodinated ¹²⁵I albumin injection

1. Indications

¹²⁵I-Albumin injection is not an approved product in the Netherlands.

Indications are determination of plasma volume and total blood volume and examination of albumin turnover.

2. Preparation

¹²⁵I-Albumin is supplied as a solution for injection.

3. Quality control

The European Pharmacopeia has a monograph for Human albumin injection, iodinated (¹²⁵I). It uses size-exclusion chromatography to determine radiochemical purity.

The monograph of the US Pharmacopeia thin-layer chromatography:

- pH = 7,0-8,5
- Radionuclidic purity: minimum 95% of total radioactivity.
- Radiochemical purity: Place a measured volume, diluted with a suitable diluent so it provides a count rate of about 20.000 counts per min, about 25 mm from one end of a 25x300 mm chromatographic paper and allow to dry. Develop over a period of about 4 h using methanol (70%) and air-dry.
- Limit: ≥97% is ¹²⁵I albumin (Rf=0).

4. Interactions

No data

5. Contraindications

Seralb[®] contains benzylalcohol, which may cause serious reactions in premature and low birth-weight infants. The European Medicines Agency (EMA) and the Dutch College ter Beoordeling van Geneesmiddelen (CBG) have published guidelines on the maximum amount of benzylalcohol that should be used. The CBG advises a maximum amount of 90 mg/kg body weight.

6. Adverse reactions

With the administration of iodinated human albumin, allergic and febrile reactions have been reported. Manifestations include fever, dizziness, nausea, vomiting, tachycardia, hypotension and urticaria.

7. Biodistribution & pharmacokinetics

Distribution Sites

¹²⁵I Iodinated albumin is uniformly distributed throughout the intravascular system within 10 min after intravenous injection. Iodinated ¹²⁵I albumin can be detected in the lymph

within 10 min after intravenous injection. Maximal distribution through this extravascular space does not occur until 2-4 days after administration.

¹²⁵I-Iodinated albumin is eliminated almost entirely in the urine. A small percentage (about 2%) of the total dose appears in the feces. In normal subjects, the biological half-life of iodinated ¹²⁵I albumin has been reported to be approximately 14 days. The half-life has varied considerably amongst published studies, ranging from less than 10 days to over 20 days. Different factors can affect the half-life of the labeled albumin. For example, the quality of the labeled albumin can affect the initial rate of excretion.

8. Stability

¹²⁵I-Albumin has a shelf-life of 49 days after manufacture. Store in a refrigerator (2-8°C).

9. Literature

- SmPC Iodinated 125I human albumin injection CIS bio international, 10/2015.
- United States Pharmacopeia monograph Iodinated I 125 albumin injection.