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# Iodinated I 131 Albumin Injection

Albumin labeled with iodine-131.

» Iodinated I 131 Albumin Injection is a sterile, buffered, isotonic solution containing normal human albumin adjusted to provide not more than 37 MBq (1 mCi) of radioactivity per mL. It is derived by mild iodination of normal human albumin with the use of radioactive iodine (<sup>131</sup>I) to introduce not more than one gram-atom of iodine for each gram-molecule (60,000 g) of albumin.

Iodinated I 131 Albumin Injection contains not less than 95.0 percent and not more than 105.0 percent of the labeled amount of <sup>131</sup>I as iodinated albumin, expressed in megabecquerels (microcuries or in millicuries) per mL at the time indicated in the labeling. Other forms of radioactivity do not exceed 3 percent of the total radioactivity. Its production and distribution are subject to federal regulations (see [Biologics \(1041\)](#) and [Radioactivity \(821\)](#)).

**Labeling**—Label it to include the following, in addition to the information specified for [Labeling \(7\)](#), [Labels and Labeling for Injectable Products](#): the date of calibration; the amount of <sup>131</sup>I as iodinated albumin, expressed as total megabecquerels (millicuries or microcuries), and concentration as megabecquerels (microcuries or millicuries) per mL on the date of calibration; the expiration date; and the statement “Caution—Radioactive Material.” The labeling indicates that in making dosage calculations, correction is to be made for radioactive decay, and also indicates that the radioactive half-life of <sup>131</sup>I is 8.08 days.

**Radionuclide identification** (see [Radioactivity \(821\)](#))—Its gamma-ray spectrum is identical to that of a specimen of <sup>131</sup>I of known purity that exhibits a major photopeak having an energy of 0.364 MeV.

**Other requirements**—It meets the requirements for [Packaging and storage](#), [Bacterial endotoxins](#), [pH](#), [Radiochemical purity](#), and [Assay for radioactivity](#) under [Iodinated I 125 Albumin Injection](#). It meets also the requirements under [Biologics \(1041\)](#), and the requirements under [Injections and Implanted Drug Products \(1\)](#), except that it is not subject to the recommendation on *Container Content*. It meets all other applicable requirements of the FDA.

**Auxiliary Information** - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
IODINATED I 131 ALBUMIN INJECTION	<a href="#">Documentary Standards Support</a>	SM42020 Small Molecules 4

**Chromatographic Database Information:** [Chromatographic Database](#)

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