Octreoscan™
Kit for the Preparation of Indium In-111 Pentetreotide

INDICATIONS AND USAGE

OctreoScan® Kit for the Preparation of Indium In-111 Pentetreotide is an agent for the scintigraphic localization of primary and metastatic neuroendocrine tumors bearing somatostatin receptors.

WARNINGS AND PRECAUTIONS

- DO NOT ADMINISTER IN TOTAL PARENTERAL NUTRITION (TPN) ADMIXTURES OR INJECT INTO TPN INTRAVENOUS ADMINISTRATIONS LINES; IN THESE SOLUTIONS, A COMPLEX GLYCOSYL OCTREOTIDE CONJUGATE MAY FORM.
- The sensitivity of scintigraphy with indium In-111 pentetreotide may be reduced in patients concurrently receiving therapeutic doses of octreotide acetate. Consideration should be given to temporarily suspending octreotide acetate therapy before the administration of indium In-111 pentetreotide and to monitoring the patient for any signs of withdrawal.
- **Therapy with octreotide acetate can produce severe hypoglycemia in patients with insulinomas. Precautions should be taken to prevent hypoglycemia in these patients.**
- **The contents of the two vials supplied with the kit are intended only for use in the preparation of indium In-111 pentetreotide and are NOT to be administered separately to the patient.**
- **As with any other radioactive material, appropriate shielding should be used to avoid unnecessary radiation exposure to the patient, occupational workers, and other persons.**
- **Radiopharmaceuticals should be used only by physicians who are qualified by specific training in the safe use and handling of radionuclides.**
- **To help reduce the radiation dose to the thyroid, kidneys, bladder, and other target organs, patients should be well hydrated before the administration of indium In-111 pentetreotide. It is also recommended that patients be given a mild laxative before and after administration of indium In-111 pentetreotide.**
- **Indium In-111 pentetreotide should be tested for labeling yield of radioactivity prior to administration. The product must be used within six hours of preparation.**
- **To maintain sterility, it is essential that directions are followed carefully. Aseptic technique must be used during the preparation and administration of indium In-111 pentetreotide.**
- **Octreotide acetate and the natural somatostatin hormone may be associated with cholelithiasis, presumably by altering fat absorption and possibly by decreasing motility of the gallbladder. A single dose of indium In-111 pentetreotide is not expected to cause cholelithiasis.**

ADVERSE REACTIONS

- Serious adverse reactions may include bradycardia and decreased hematocrit and hemoglobin (one reported case of each in clinical trials involving 538 patients).
- Adverse effects observed at a rate less than 1% of 538 patients include dizziness, fever, flush, headache, hypotension, changes in liver enzymes, joint pain, nausea, sweating, and weakness. These adverse effects were transient.

- False Positive/ False Negative Results: From the clinical trials, overall, including all tumor types with or without the presence of somatostatin receptors, there were 3/508 false positives and 104/508 false negatives.
- Pentetreotide is derived from octreotide which is used as a therapeutic agent to control symptoms from certain tumors. The usual dose for indium In-111 pentetreotide is approximately 5 to 20 times less than for octreotide and is subtherapeutic.
  - Common adverse reactions of octreotide include nausea, injection site pain, diarrhea, abdominal pain/discomfort, loose stools, and vomiting.
  - Hypertension and hyper- and hypoglycemia have also been reported with the use of octreotide.

USE IN SPECIFIC POPULATIONS

- Breast feeding: It is not known if this drug is excreted in human milk, caution should be exercised when indium In-111 pentetreotide is administered to a nursing woman.
- Pediatrics: Safety and effectiveness have not been established in pediatric patients.
- **Since indium In-111, pentetreotide is eliminated primarily by renal excretion, use in patients with impaired renal function should be carefully considered.**