

RADIOPHARMACEUTICAL IMAGING AND APPENDICITIS

If you or a loved one has suffered an adverse cardiopulmonary event such as cardiac arrest, hypoxia, dyspnea, and hypotension or death after being injected with a radiopharmaceutical imaging agent to detect appendicitis, contact Eichen Levinson for a free consultation.

FDA Public Health Advisory

Suspended Marketing of NeutroSpec (Technetium (99m Tc) fanolesomab)

FDA is issuing this public health advisory to inform patients and health care providers that Palatin Technologies, the manufacturer of NeutroSpec (Technetium (99m Tc) fanolesomab) is voluntarily suspending marketing of NeutroSpec effective immediately due to serious safety concerns. NeutroSpec is indicated for radiologic imaging of patients with unclear signs and symptoms of appendicitis who are five years of age and older.

FDA received reports from Palatin Technologies of 2 deaths and 15 additional life-threatening adverse events in patients receiving NeutroSpec. These events occurred within minutes of administration of NeutroSpec and included shortness of breath, low blood pressure, and cardiopulmonary arrest. Affected patients required resuscitation with intravenous fluids, blood pressure support, and oxygen. Most, but not all, of the patients who experienced these events had existing cardiac and/or pulmonary conditions that may have placed them at higher risk for these adverse events. A review of all post-marketing reports showed an additional 46 patients who experienced adverse events that were similar but less severe. All of the reactions occurred immediately after NeutroSpec was administered. There is no evidence that patients who already safely received the drug face any long-term risk.

The relationship between NeutroSpec and these events has not been definitively determined. However, the consistent characteristics and rapid onset of these events following NeutroSpec injection makes it likely that they were due to administration of NeutroSpec. NeutroSpec is an antibody radio-labeled with technetium-99m. There is no indication that the radiopharmaceutical component of NeutroSpec, technetium-99m, was related to occurrence of these events.

The decision to suspend marketing was based on the life-threatening nature of the events and the availability of other means to diagnose appendicitis that do not carry these risks. FDA urges health care providers to discontinue use of existing stocks of NeutroSpec and to contact Palatin Technologies regarding their return.

NeutroSpec was approved in June 2004 for imaging of patients with equivocal signs and symptoms of appendicitis who are five years of age or older. Market approval was based on a total of 523 subjects; and adverse events of the severity described above were not observed pre-marketing. The 17 patients who experienced the serious events received NeutroSpec to diagnose infections other than appendicitis.