Mallinckrodt issues warning after deaths attributed to NeutroSpec

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Palatin Technologies of Cranbury, NJ, and Tyco Mallinckrodt Healthcare, a unit of Tyco International, issued a warning about the deaths Nov. 30. According to the announcement, Mallinckrodt received reports of the two deaths and additional cases of serious cardiopulmonary adverse reactions including cardiac arrest, hypoxia, and hypotension. The deaths and severe reactions happened within 30 minutes of injection. The onset, according to the announcement, generally occurred within minutes of injection and required resuscitation with fluids, vasopressors, and oxygen. A majority of the incidents involved patients with underlying cardiopulmonary disease and off-label applications, the company said. The company did not disclose the number of non-fatal adverse events.

The firm warned physicians that patients receiving NeutroSpec should be closely monitored for at least one hour after administration. Resuscitation equipment and appropriately-trained personnel should be readily available during that time.

The firm said it is working with the FDA to review cases and revise safety information on its package labeling. The FDA posted a notice about the incidents on its Web site on Dec. 1.

NeutroSpec is indicated for scintigraphic imaging of patients with equivocal symptoms of appendicitis who are at least five years of age. The technetium-labeled anti-CD15 monoclonal antibody selectively binds to neutrophils (a type of white blood cell) involved in immune response. The FDA approved NeutroSpec for diagnosis of equivocal appendicitis in July 2005. It was the first agent related to noninvasive diagnosis of infection to be approved by the agency in more than two decades.

Disclosures:

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