FDA Alert for Healthcare Professionals

NeutroSpec™ [Technetium (99m Tc) fanolesomab]

This product is not currently available for purchase in the U.S.

FDA ALERT [12/2005]: NeutroSpec Marketing Voluntarily Suspended.

Palatin Technologies and the FDA have agreed on the immediate suspension of sales and marketing of NeutroSpec [Technetium (99m Tc) fanolesomab] in the United States, due to reports of serious and life-threatening cardiopulmonary events following the administration of the drug. NeutroSpec is used for radionuclide imaging of patients with equivocal signs and symptoms of appendicitis. NeutroSpec has also been used for certain unapproved indications, such as the detection of osteomyelitis and other infections. Onset of these serious events generally occurred within minutes of administering the drug and there have been two deaths attributed to cardiopulmonary failure. Patients have experienced other serious cardiopulmonary events, including cardiac arrest, hypoxia, dyspnea and hypotension, and required resuscitation with fluids, vasopressors, and oxygen. 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.

This information reflects FDA's current analysis of data concerning this drug. FDA intends to update this sheet when additional information or analyses become available.

To report any unexpected adverse or serious events associated with the use of this drug, please contact the FDA MedWatch program at 1-800-FDA-1088 or http://www.fda.gov/medwatch/report/hcp.htm

Recommendations

- Healthcare providers should discontinue use of NeutroSpec and contact the manufacturer about returning existing stocks.
- Healthcare providers should evaluate patients who received NeutroSpec previously, and report any adverse events in such patients to MedWatch (see above).
- Any patient who receives NeutroSpec despite this advisory must be closely monitored for at least one hour following product administration. Resuscitation equipment and appropriately trained personnel must be readily available during this time. Patients

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with underlying cardiopulmonary conditions may be at higher risk for serious complications.

Data Summary

NeutroSpec™ [Technetium (99m Tc) fanolesomab] is a radiodiagnostic agent consisting of a murine (mouse) IgM monoclonal antibody and technetium, the radioactive component. Following intravenous administration, the drug collects in areas with high concentrations of white blood cells, such as areas of infection and/or inflammation. NeutroSpec was approved in 2004 for use in the scintigraphic imaging of patients with equivocal signs and symptoms of appendicitis who are five years of age or older.

Post-marketing reports include serious adverse events in 17 patients, two of whom died. Both patients who died were diabetics. Of the 15 patients who recovered, three were treated in intensive care units, two required cardio-pulmonary resuscitation, and five received oxygen. The serious adverse events generally occurred within minutes after the drug was administered. An additional 46 patients experienced less serious adverse events also involved effects on breathing and blood pressure (specifically hypoxia, hypotension, and dyspnea).

NeutroSpec is approved by the FDA only for the diagnosis of appendicitis in cases where the usual signs and symptoms are unclear, but it is often used for diagnosing infections other than appendicitis. None of the post-marketing serious adverse events occurred in patients suspected of appendicitis. However, adverse events of a similar pattern but of lesser severity have been reported among patients with suspected appendicitis.. The decision to suspend sales and marketing of NeutroSpec was based on the life-threatening nature of the adverse events and the availability of other methods of diagnosing appendicitis among patients with equivocal signs and symptoms of this infection.

Before approval, NeutroSpec was studied for safety in 523 subjects, including both patients and healthy volunteers. In the pre-marketing studies, uncommon cardiopulmonary adverse events were detected but serious cardiopulmonary adverse events of the type detected following NeutroSpec approval were not observed. The post-approval clinical data are not sufficient to identify patients at higher risk of serious cardiopulmonary adverse events. The FDA will work closely with Palatin Technologies to evaluate the adverse events and whether further studies might be needed to develop safer uses of NeutroSpec. The FDA will notify health care providers and the public as new information becomes available.

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