

November 30, 2005

## IMPORTANT DRUG WARNING

Dear Healthcare Provider:

Mallinckrodt and Palatin Technologies Inc. are writing to inform you of postmarketing reports of serious and life-threatening cardiopulmonary events following the administration of NeutroSpec™ [Technetium (99m Tc) fanolesomab].

Mallinckrodt has been informed of two deaths attributed to cardiopulmonary failure within 30 minutes of injection and additional cases of serious cardiopulmonary events including cardiac arrest, hypoxia, dyspnea and hypotension. Onset of these events generally occurred within minutes of injection and required resuscitation with fluids, vasopressors, and oxygen. The majority of these reports described patients with underlying cardiopulmonary disease who received NeutroSpec™ for unapproved indications. However, any patient who receives NeutroSpec™ should 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 with underlying cardiopulmonary conditions may be at higher risk for serious complication. NeutroSpec™ administration to these patients should only follow careful consideration of the known and potential risks and benefits, including the possibly higher risks.

We are working with the Food and Drug Administration (FDA) to review these cases and revise the NeutroSpec™ U.S. package insert to provide additional Warnings and safety information. We intend to provide you with updated information once the review is complete.

NeutroSpec™ is indicated for scintigraphic imaging of patients with equivocal signs and symptoms of appendicitis who are five years of age or older. Please see the Warnings section in the enclosed NeutroSpec™ package insert regarding the risk for anaphylaxis and other types of hypersensitivity reactions.

For any questions, to request more information, or to report serious adverse events suspected to be associated with the use of NeutroSpec™, call 888-744-1414. Alternatively, adverse event information may be reported directly to the Food and Drug Administration's MedWatch Reporting System by phone at **1-800-FDA-1088**, by facsimile to 1-800-FDA-0178, by mail using Form 3500 at <http://www.fda.gov/medwatch/index.html>.

As a reminder, a single patient dose of NeutroSpec™ for imaging contains 75 to 125 mcg of fanolesomab labeled with 10 to 20 mCi (370 to 740 MBq) Sodium Pertechnetate Tc 99m Injection, USP. Please refer to the enclosed PI for the current full Prescribing Information for NeutroSpec™.

Sincerely,



Herbert R. Neuman, MD  
Director, Global Drug Safety and Pharmacovigilance  
Mallinckrodt



Stephen T. Wills  
Executive Vice President, Operations  
Palatin Technologies, Inc.