

SPINE SAFETY NOTICE:

Information for Healthcare Professionals:

Vancomycin Hydrochloride® (vancomycin hydrochloride) Injection, Solution for Intravenous Use Only

Important Revisions to the Prescribing Information

According to MedWatch, modifications have been made to the WARNINGS and PRECAUTIONS sections of Vancomycin Hydrochloride® (vancomycin hydrochloride) Injection, Solution for Intravenous Use Only labeling. The revised WARNINGS and PRECAUTIONS sections now address *Clostridium difficile* associated diarrhea (CDAD) and provides information for patients related to the importance of contacting their physicians.

Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including Vancomycin Hydrochloride® (vancomycin hydrochloride) Injection, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C. difficile*. *C. difficile* produces toxins A and B which contribute to the development of CDAD. Hypertoxin producing strains of *C. difficile* cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents. If CDAD is suspected or confirmed, ongoing antibiotic use not directed against *C. difficile* may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of *C. difficile*, and surgical evaluation should be instituted as clinically indicated.

The complete MedWatch Safety Labeling Changes, including links to prescribing information, are available at:

<http://www.fda.gov/medwatch/SAFETY/2007/sep07.htm>

The North American Spine Society is committed to quality patient care through promotion of patient safety and prevention of medical errors. NASS monitors a variety of government and other resources for patient safety related notices that may be useful to our members. Information from these notices is also archived on the NASS Web site at http://www.spine.org/spine_safety_notices.cfm. This information is provided as a service for information and education only.