SPINE SAFETY WARNING:

Information for Healthcare Professionals:
Zyvox (linezolid)
Drug Safety Communication - Serious CNS Reactions Possible When Given to Patients Taking Certain Psychiatric Medications

SOURCE: FDA MedWatch

ISSUE: FDA has received reports of serious central nervous system (CNS) reactions when the antibacterial drug linezolid (Zyvox) is given to patients taking psychiatric medications that work through the serotonin system of the brain (serotonergic psychiatric medications. A list of the serotonergic psychiatric medications that can interact with linezolid can be found in the Drug Safety Communication. Safety information about this potential drug interaction and important drug usage recommendations for emergency and non-emergency situations are being added to the drug labels for serotonergic psychiatric medications and linezolid.

BACKGROUND: Linezolid is used to treat infections, including pneumonia, infections of the skin, and infections caused by a resistant bacterium (Enterococcus faecium). It is a reversible monoamine oxidase inhibitor (MAOI). Although the exact mechanism of this drug interaction is unknown, linezolid inhibits the action of monoamine oxidase A — an enzyme responsible for breaking down serotonin in the brain. It is believed that when linezolid is given to patients taking serotonergic psychiatric medications, high levels of serotonin can build up in the brain, causing toxicity. This is referred to as Serotonin Syndrome — signs and symptoms include mental changes (confusion, hyperactivity, memory problems), muscle twitching, excessive sweating, shivering or shaking, diarrhea, trouble with coordination and/or fever.

A separate Drug Safety Communication (DSC) is being released today for methylene blue due to similar potential drug interactions with serotonergic psychiatric medications and includes drug usage recommendations.

RECOMMENDATION: Linezolid should generally not be given to patients taking serotonergic drugs. However, there are some conditions that may be life-threatening or require urgent treatment with linezolid such as when:

- Linezolid is used to treat vancomycin-resistant Enterococcus faecium (VRE) infections.
- Linezolid is used to treat infections such as nosocomial pneumonia and complicated skin and skin structure infections, including cases caused by methicillin-resistant Staphylococcus aureus (MRSA).

Patients should not stop taking their serotonergic psychiatric medicine without first talking to a healthcare professional. Read the Drug Safety Communication for other specific recommendations for Healthcare Professionals and for Patients.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Read the MedWatch safety alert, including a link to the FDA Drug Safety Communication, at:

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm265479.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 website at http://www.spine.org/Pages/PracticePolicy/ClinicalCare/SpineSafetyAlerts/Default.aspx. This information is provided as a service for information and education only.