

SPINE SAFETY WARNING:

Information for Healthcare Professionals:

Methylene Blue

Drug Safety Communication - Serious CNS Reactions Possible When Given to Patients Taking Certain Psychiatric Medications

- ❖ **Note from NASS' Patient Safety Committee Chairs:**
Methylene Blue is used to mark disc tissue when injected into the disc prior to an endoscopic or laser discectomy.

SOURCE: FDA MedWatch

ISSUE: FDA has received reports of serious central nervous system (CNS) reactions when the drug methylene blue 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 methylene blue 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.

BACKGROUND: Methylene blue is used to treat methemoglobinemia, vasoplegic syndrome, ifosfamide-induced encephalopathy, and cyanide poisoning. It is also used as a dye in therapeutic and diagnostic applications. Methylene blue is a potent, reversible monoamine oxidase inhibitor (MAOI). Although the exact mechanism of this drug interaction is unknown, methylene blue inhibits the action of monoamine oxidase A — an enzyme responsible for breaking down serotonin in the brain. It is believed that when methylene blue 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 Zyvox (linezolid) due to similar potential drug interactions with serotonergic psychiatric medications and includes drug usage recommendations.

RECOMMENDATION: Methylene blue 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 methylene blue such as when it is used in the emergency treatment of methemoglobinemia, ifosfamide-induced encephalopathy, or cyanide poisoning.

Patients should not stop taking their serotonergic psychiatric medicine without first talking to a healthcare professional. Read the Drug Safety Communication below 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/ucm265476.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.