

SPINE SAFETY NOTICE:

Updated Prescribing Information for **Paroxetine HCl - Paxil®/Paxil CR and generic paroxetine**

On December 8, 2005, the U.S. Food and Drug Administration (FDA) determined that exposure to paroxetine in the first trimester of pregnancy may increase the risk for congenital malformations, particularly cardiac malformations. At the FDA's request, the manufacturer has changed paroxetine's pregnancy category from C to D and added new data and recommendations to the WARNINGS section of paroxetine's prescribing information. FDA is awaiting the final results of the recent studies and accruing additional data related to the use of paroxetine in pregnancy in order to better characterize the risk for congenital malformations associated with paroxetine.

Physicians who are caring for women receiving paroxetine should alert them to the potential risk to the fetus if they plan to become pregnant or are currently in their first trimester of pregnancy. Discontinuing paroxetine therapy should be considered for these patients. Women who are pregnant, or planning a pregnancy, and currently taking paroxetine should consult with their physician about whether to continue taking it. Women should not stop the drug without discussing the best way to do that with their physician.

You may access the MedWatch 2005 Safety Summary, including links to the FDA Public Health Advisory and the FDA Drug Information Page that includes links to the Healthcare Professional and Patient Information Sheets, at:

<http://www.fda.gov/medwatch/safety/2005/safety05.htm#Paxil3>.

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.