

SPINE SAFETY NOTICE:

Information for Healthcare Professionals:

Norpramin® (desipramine hydrochloride tablets, USP)

According to MedWatch, modifications have been made to the WARNINGS and PRECAUTIONS sections of Nopramin® labeling, a black box warning has been added, and the medication guide has been updated. The revised labeling now addresses the increased risk, compared to placebo, of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of Norpramin® or any other antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older. Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior.

The complete MedWatch 2007 Safety Labeling Changes, including links to the updated prescribing information, medication guide, FDA Press Release and Antidepressant Information Page regarding this issue, is available at:

<http://www.fda.gov/medwatch/SAFETY/2007/jul07.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/spine_safety_notices.cfm. This information is provided as a service for information and education only.