

## SPINE SAFETY WARNING:

### **Information for Healthcare Professionals: Enbrel (etanercept)- Prescribing Information Revised To Include A Boxed Warning Regarding The Risk Of Infection, Including Tuberculosis**

According to MedWatch, Amgen and Wyeth Pharmaceuticals informed healthcare professionals of revisions to prescribing information for Enbrel. The revisions include a BOXED WARNING about infections, including serious infections leading to hospitalization or death that have been observed in patients treated with Enbrel. Infections have included bacterial sepsis and tuberculosis. The ADVERSE REACTIONS section of the label was updated to include information regarding global clinical studies and the rate of occurrence of tuberculosis in patients treated with Enbrel. Healthcare professionals should screen patients for latent tuberculosis infection before beginning Enbrel. Patients should be educated about the symptoms of infection and closely monitored for signs and symptoms of infection during and after treatment with the drug. Patients who develop an infection should be evaluated for appropriate antimicrobial treatment and, in patients who develop a serious infection, Enbrel should be discontinued.

Read the entire 2008 MedWatch Safety Summary, including a link to the manufacturer's Dear Healthcare Professional Letter regarding this issue at:  
<http://www.fda.gov/medwatch/safety/2008/safety08.htm#Enbrel>

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/Pages/PracticePolicy/ClinicalCare/SpineSafetyAlerts/Default.aspx>. This information is provided as a service for information and education only.