

SPINE SAFETY CAUTIONARY NOTICE:

Information for Healthcare Professionals:

Tumor Necrosis Factor-alpha (TNF α) Blockers: Label Change - Boxed Warning Updated for Risk of Infection from Legionella and Listeria

Includes Remicade (infliximab), Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab pegol), and Simponi (golimumab)

SOURCE: FDA MedWatch

ISSUE: FDA notified healthcare professionals that the Boxed Warning for the entire class of Tumor Necrosis Factor-alpha (TNF α) blockers has been updated to include the risk of infection from two bacterial pathogens, Legionella and Listeria. In addition, the Boxed Warning and Warnings and Precautions sections of the labels for all of the TNF α blockers have been revised so that they contain consistent information about the risk for serious infections and the associated disease-causing pathogens.

Patients treated with TNF α blockers are at increased risk for developing serious infections involving multiple organ systems and sites that may lead to hospitalization or death due to bacterial, mycobacterial, fungal, viral, parasitic, and other opportunistic pathogens.

BACKGROUND: The class of TNF α blockers are used to treat Crohn's disease, ulcerative colitis, rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, plaque psoriasis, and/or juvenile idiopathic arthritis.

RECOMMENDATION: The risks and the benefits of TNF α blockers should be considered prior to initiating therapy in patients with chronic or recurrent infection and patients with underlying conditions that may predispose them to infection. See the Drug Safety Communication for a listing of recommendations for healthcare professionals and patients, as well as a data summary.

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/ucm270977.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.