

SPINE SAFETY CAUTIONARY NOTICE:

Information for Healthcare Professionals: Serious Fungal Infections with Humira, Cimzia, Enbrel and Remicade

According to MedWatch, the manufacturers of Humira (adalimumab), Cimzia (certolizumab pegol), Enbrel (etanercept), and Remicade (infliximab) must strengthen warnings about the risk of developing opportunistic fungal infections from these drugs. These infections have been fatal in some patients.

Humira, Cimzia, Enbrel, and Remicade are tumor necrosis factor alpha blockers (TNF blocker) which suppress the immune system. These drugs are approved to treat one or more of several diseases, including juvenile idiopathic arthritis, rheumatoid arthritis, psoriatic arthritis, plaque psoriasis, Crohn's disease, and ankylosing spondylitis.

The labeling for these drugs already includes warnings about the risk of serious infections, including fungal infections. But based on reports reviewed by FDA, cases of histoplasmosis and other invasive fungal infections have not been recognized consistently, and that has delayed antifungal treatment and led to death in some patients.

Healthcare providers should be alert to the risk of invasive fungal infections in patients being treated with TNF blockers, especially those who live or have traveled in areas where mycoses are endemic (e.g., the Ohio River and Mississippi River Valleys).

Patients who develop a fungal infection should stop TNF blocker therapy. They may be able to restart treatment after recovering from the infection, and after the benefits and risks of further treatment are evaluated. This evaluation is especially important for patients who live in areas where mycoses are commonly found.

Additional Information:

FDA MedWatch Safety Alert. Tumor necrosis factor-alpha blockers (TNF blockers), Cimzia (certolizumab pegol), Enbrel (etanercept), Humira (adalimumab), and Remicade (infliximab). September 4, 2008.
<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01879.html>

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>

[t.aspx](#). This information is provided as a service for information and education only.