

# IMPORTANT DRUG WARNING

Dear Healthcare Provider:

UCB, Inc., the makers of CIMZIA<sup>®</sup> (certolizumab pegol), would like to notify you about the risk of invasive fungal infections, including histoplasmosis, associated with tumor necrosis factor alpha (TNF $\alpha$ ) blockers. On September 4, 2008, the FDA issued an Alert to healthcare providers regarding TNF $\alpha$  blockers. The FDA reported histoplasmosis and other invasive fungal infections are not consistently recognized in patients taking the TNF $\alpha$  blockers: CIMZIA (certolizumab pegol), Enbrel<sup>®</sup> (etanercept), Humira<sup>®</sup> (adalimumab), and Remicade<sup>®</sup> (infliximab).<sup>1</sup> This has resulted in delays in appropriate antifungal treatment, sometimes resulting in death.

CIMZIA (certolizumab pegol) is indicated for reducing signs and symptoms of Crohn's disease and maintaining clinical response in adult patients with moderately to severely active disease that have had an inadequate response to conventional therapy.<sup>2</sup>

Important information about the risk of invasive fungal infections, such as histoplasmosis, is listed in the *Boxed Warning* and *Warnings sections* of CIMZIA's prescribing information and the Medication Guide for patients.

**The following information is important for healthcare providers and patients treated with TNF $\alpha$  blockers:**

- *These patients are at risk for developing infections including invasive fungal infections such as histoplasmosis, coccidioidomycosis, blastomycosis, candidiasis, aspergillosis, pneumocystosis, and other opportunistic fungal infections.*
- *For patients who reside or travel in regions where mycoses are endemic (e.g., Ohio and Mississippi River valleys), invasive fungal infection should be suspected if they develop a serious systemic illness.*
- *Patients should report and be closely monitored during and after treatment with TNF $\alpha$  blockers for the development of any signs and symptoms of invasive fungal*

*infection including fever, malaise, weight loss, sweats, cough and dyspnea, pulmonary infiltrates on X-ray or serious systemic illness.*

- *Patients who develop an infection, including any persistent or reoccurring infections should have their TNF $\alpha$  blocker discontinued and undergo a complete diagnostic workup. Empiric antifungal therapy should be considered until the pathogen(s) are identified and in consultation with an infectious diseases specialist when feasible.*
- *TNF $\alpha$  blockers may be restarted after recovery from the infection based on a reevaluation of risks and benefits. The decision to restart TNF $\alpha$  blocker therapy and the duration of the antifungal therapy should be made in consultation with an infectious diseases specialist when feasible.*

For further information please refer to the following FDA links:

[http://www.fda.gov/cder/drug/InfoSheets/HCP/TNF\\_blockersHCP.htm](http://www.fda.gov/cder/drug/InfoSheets/HCP/TNF_blockersHCP.htm)  
<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01879.html>

PLEASE NOTE: This letter does not include a comprehensive description of the serious and significant risks associated with the use of CIMZIA. Please read the accompanying full prescribing information and Medication Guide for a complete description of the serious and significant risks associated with the use of CIMZIA, including the Boxed Warning regarding the risk of serious infections, *Contraindications, Warnings, Precautions and Adverse Events.*

Healthcare professionals should report cases of serious fungal infections or any serious adverse events suspected to be associated with the use of CIMZIA at 1-866-822-0068. Alternatively, report this information to FDA's MedWatch reporting system by phone (1-800-FDA-1088), by facsimile (1-800-FDA-0178), online (<https://www.accessdata.fda.gov/scripts/medwatch/>) or mailed, using the MedWatch for FDA 3500, to the FDA Medical Products Reporting Program, 5600 Fishers Lane, Rockville, MD 20852-9787.

If you have any questions, please contact UCB Medical Information at 866-822-0068, option 9.

Sincerely,

Kathleen Bos, MD  
Vice-President, US Medical Affairs  
UCB Inc.

References:

1. Information for Healthcare Professional CIMZIA (certolizumab pegol), Enbrel<sup>®</sup> (etanercept), Humira<sup>®</sup> (adalimumab), and Remicade<sup>®</sup> (infliximab).

[http://www.fda.gov/cder/drug/InfoSheets/HCP/TNF\\_blockersHCP.htm](http://www.fda.gov/cder/drug/InfoSheets/HCP/TNF_blockersHCP.htm). Accessed September 25, 2008.

2. CIMZIA (certolizumab pegol) [package insert]. Smyrna, GA: UCB; 2008.