IMPORTANT SAFETY INFORMATION

MEDSAFE
NEW ZEALAND MEDICINES
AND MEDICAL DEVICES
SAFETY AUTHORITY
A BUSINESS UNIT OF
THE MINISTRY OF HEALTH
www.medsafe.govt.nz

08 November 2006

Dear Healthcare Professional,

Re: Hepatitis B reactivation associated with the anti-TNF products, ENBREL® (etanercept), HUMIRA® (adalimumab) and REMICADE® (infliximab)

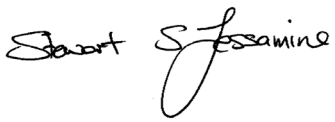
- **Hepatitis B virus (HBV) reactivation has been reported in patients receiving the anti-TNF agents, ENBREL®, HUMIRA®, and REMICADE®.**
- **Patients at risk for HBV infection should be evaluated for evidence of prior HBV infection before anti-TNF therapy is initiated.**
- **Patients identified as carriers of HBV infection should be closely monitored for signs and symptoms of reactivated HBV infection throughout the course of anti-TNF therapy, and for several months following termination of therapy.**
- **Anti-TNF therapy should be discontinued in patients who develop reactivation of HBV infection.**

Very rare cases of hepatitis B virus (HBV) reactivation associated with anti-tumour necrosis factor (anti-TNF) therapy have been reported internationally. In some instances, the reactivation of HBV infection was fatal. In the majority of cases, patients were receiving concomitant treatment with other immunosuppressants; therefore a causal relationship with anti-TNF agents is confounded by the presence of these other medicines.

Patients at risk for HBV infection should be evaluated for evidence of prior HBV infection before anti-TNF therapy is initiated. Patients who are carriers of HBV and require treatment with anti-TNF agents should be closely monitored for signs and symptoms of reactivated HBV infection throughout therapy and for several months following termination of therapy. In patients who develop HBV reactivation, the anti-TNF agent should be stopped and effective anti-viral therapy with appropriate supportive treatment should be initiated.

The New Zealand data sheets for ENBREL®, HUMIRA®, and REMICADE® have been updated to include the above safety information and are available on the Medsafe web site (www.medsafe.govt.nz/DatasheetPage.htm).

Please report any case of HBV reactivation or other serious or unexpected adverse reactions in patients receiving anti-TNF agents to: CARM, NZ Pharmacovigilance Centre, PO Box 913, Dunedin. Such post-marketing reports are valuable in enabling a more accurate quantification of risk and in providing a New Zealand perspective on emerging medicines safety issues.



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