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IN BRIEF

Anaphylaxis with Omalizumab *(Xolair)*

The FDA has received new reports of serious and life-threatening hypersensitivity reactions to omalizumab (*Xolair* – Genentech), a monoclonal anti-IgE antibody injected subcutaneously for treatment of asthma (Med Lett Drugs Ther 2003; 45:67), and has added a black-box warning to the package insert.

Postmarketing reports submitted to the FDA included 124 reports of anaphylaxis among an estimated 57,300 patients (0.2%) who might have been treated with the drug between June 2003 and December 2006. Anaphylaxis occurred after the first dose of *Xolair* in 39% of cases, after a 2nd dose in 19%, after a 3rd dose in 10% and after subsequent doses in the rest; one case occurred after 39 doses (19 months of continuous therapy) when treatment was restarted after a 3-month gap. Most cases (59%) occurred within 2 hours of the injection, but 32% occurred later, up to 4 days after the injection. No deaths have been reported (www.fda.gov/cder/drug/infopage/omalizumab).

Use of omalizumab should be limited to patients with severe asthma that is not adequately controlled by other drugs and has a clear allergic component. Patients should be observed for 2 hours after injection in a setting where anaphylaxis can be diagnosed and treated promptly and should carry an epinephrine autoinjector *(EpiPen; Twinject)* for a few days following an injection.

Coming Soon in *The Medical Letter*:
Reducing Intake of Trans Fatty Acids
Lybrel — A New Contraceptive Pill
Lapatinib *(Tykerb)* for Breast Cancer

Coming Soon in *Treatment Guidelines*:
Drugs for Allergic Disorders — August 2007
Drugs for Sexually Transmitted Infections — September 2007
Drugs for COPD — October 2007

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