The Medical Letter®

On Drugs and Therapeutics

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Happy New Year

This is the last issue of 2011. The first issue of 2012 will be dated January 9th.

IN BRIEF

Xigris Withdrawn

The FDA has announced that Eli Lilly has voluntarily withdrawn drotrecogin alfa (activated) *(Xigris)* after a recently completed trial (PROWESS-SHOCK) in patients with severe sepsis and septic shock failed to show an increase in survival in those treated with the drug.[1] Drotrecogin alfa is a recombinant form of human activated protein C. Native activated protein C inhibits coagulation, increases fibrinolysis and has anti-inflammatory properties. FDA approval of *Xigris* (for patients with severe sepsis at high risk of death) was based on a single study (PROWESS).[2] Post-marketing studies found a higher rate of bleeding than that reported in PROWESS.[3,4]

1. FDA Drug Safety Communication: voluntary market withdrawal of Xigris [drotrecogin alfa (activated)] due to failure to show a survival benefit. Available at http://www.fda.gov/Drugs/DrugSafety/ucm277114. htm. Accessed December 1, 2011.
2. Activated protein C (Xigris) for severe sepsis. Med Lett Drugs Ther 2002; 44:17.
3. E Abraham et al. Drotrecogin alfa (activated) for adults with severe sepsis and a low risk of death. N Engl J Med 2005; 353:1332.
4. KM Rowan et al. Drotrecogin alfa (activated): real-life use and outcomes for the UK. Crit Care 2008; 12:R58.

