Generic Name:
Drotrecogin alfa
Trade Name:
Xigris
Company:
Eli Lilly
Notes:

Drotrecogin alfa (activated) is being withdrawn from worldwide markets following release of results of the PROWESS-SHOCK study, which showed that use of the drug did not result in a statistically significant reduction in 28-day all-cause mortality in patients with septic shock, according to a Lilly news release. Timothy Garnett, MD, Lilly's Senior Vice President and Chief Medical Officer, stated in the release, ?While there were no new safety findings, the study failed to demonstrate that Xigris improved patient survival and thus calls into question the benefit?risk profile of Xigris and its continued use. Patients currently receiving treatment with Xigris should have treatment discontinued, and Xigris treatment should not be initiated for new patients."

Drotrecogin alfa was originally approved in the United States in November 2001 for the reduction of mortality in adult patients with severe sepsis who have a high risk of death (e.g., as determined by APACHE II). Heath providers with questions about the removal of drotrecogin alfa from the market are directed to contact the Lilly Answer Center at 800-LillyRx or visit the company online. In the United States and Puerto Rico, BioCritica, Inc. has had sales and marketing rights for Xigris.

Medication Monitor Categories:
Product Withdrawals