

Important Safety Information on Xigris™ (drotrecogin alfa [activated])

Xigris is approved for the reduction of mortality in adult patients with severe sepsis (sepsis associated with acute organ dysfunction) who have a high risk of death (e.g., as determined by APACHE II¹). The efficacy of Xigris has not been established in adult patients with severe sepsis and lower risk of death. Safety and efficacy have not been established in pediatric patients with severe sepsis.

Bleeding events are common in patients with severe sepsis. Bleeding is the most common adverse reaction associated with Xigris therapy. In the Phase 3 study, serious bleeding events were observed during the 28-day study period in 3.5 percent of Xigris-treated and 2.0 percent of placebo-treated patients. The difference in serious bleeding occurred primarily during infusion. Intracranial hemorrhage (ICH) may occur in patients with severe sepsis. In PROWESS, the incidence of intracranial hemorrhage was 0.2 percent for Xigris-treated and 0.1 percent for placebo-treated patients. ICH has been reported in Xigris-treated patients in non-placebo controlled trials with an incidence of approximately 1 percent during infusion. The risk of ICH may be increased in patients with risk factors for bleeding such as severe coagulopathy and severe thrombocytopenia.

Please see complete prescribing information for Contraindications, Warnings, and Precautions.

1. Acute Physiology and Chronic Health Evaluation Score

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Xigris™ is indicated for the reduction of mortality in adult patients with severe sepsis (sepsis associated with acute organ dysfunction) who have a high risk of death (e.g., as determined by APACHE II). See important safety information on Xigris™ included in this kit or on www.aboutXigris.com. Complete prescribing information for Xigris™ is enclosed in this kit.

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