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IN BRIEF

Andexanet alfa (*Andexxa*) Withdrawn

Andexanet alfa (*Andexxa* – AstraZeneca), which received accelerated approval from the FDA in 2018 for urgent reversal of the anticoagulant effect of the direct factor Xa inhibitors apixaban *(Eliquis)* and rivaroxaban *(Xarelto)*, has voluntarily been withdrawn from the market.[1] *Andexxa* was the only drug FDA-approved for this indication in the US.

Accelerated approval of andexanet alfa was based on its effect on anti-activated factor Xa activity, a surrogate endpoint.[1] The drug improved hemostasis in a confirmatory trial in patients with severe intracranial bleeding, but it was associated with an increased rate of thrombosis. Based on these results, the FDA declined to grant *Andexxa* full approval.[2]

Alternatives to andexanet alfa for reversing factor Xa inhibitor activity include four-factor prothrombin complex concentrates (PCC; *Kcentra*, *Balfaxar*) and anti-inhibitor coagulant complex *(FEIBA)*. ■

1. Andexxa – an antidote for apixaban and rivaroxaban. Med Lett Drugs Ther 2018; 60:99.
2. FDA Briefing Document. Andexxa (coagulation factor Xa (recombinant), inactivated-zhzo). Cellular, Tissue, and Gene Therapies Advisory Committee Meeting, November 21, 2024. Available at: https://bit.ly/4qjzCko. Accessed December 19, 2025.

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