

New Drug Approvals

Generic Name (Trade Name—Company)

May 7, 2018

Coagulation factor Xa (recombinant), inactivated-zhzo

(*Andexxa—Portola*)

FDA approves first and only antidote for reversal of Factor Xa inhibitors

Uses/Notes

FDA has [approved](#) coagulation factor Xa (recombinant), inactivated-zhzo, the first and only antidote indicated for patients treated with rivaroxaban and apixaban, when reversal of anticoagulation is needed because of life-threatening or uncontrolled bleeding.

The agent is a recombinant protein specifically designed to bind to Factor Xa inhibitors and rapidly reverse their anticoagulant effect. A modified form of the human Factor Xa molecule, it works by acting as a decoy for oral and injectable Factor Xa inhibitors, which target and bind to Factor Xa, which allows them to exert their anticoagulant effect. When the agent is given to a patient with Factor Xa inhibitor-related bleeding, it binds to the Factor Xa inhibitor and prevents it from inhibiting the activity of Factor Xa and reverses the anticoagulant effects of the inhibitor.

Approval was supported by data from two Phase III ANNEXA studies (ANNEXA-R and ANNEXA-A) that evaluated its safety and efficacy in reversing the anticoagulant activity of the Factor Xa inhibitors rivaroxaban and apixaban in healthy volunteers. Results demonstrated that the agent rapidly and significantly reversed anti-Factor Xa activity. The median decrease in anti-Factor Xa activity from baseline was 97% for rivaroxaban and 92% for apixaban.

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