

Coagadex approved for rare clotting disorder

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(HealthDay)—Coagadex (coagulation Factor X) has been approved by the U.S. Food and Drug Administration as the first coagulation factor replacement therapy for people with a rare blood disorder known as hereditary Factor X deficiency.

The Factor X protein normally helps blood clot. But among people with the inherited disorder, the blood doesn't clot, which can lead to dangerous bleeding episodes. Traditional treatments are based on plasma-derived products containing vitamin K-dependent proteins to stem or prevent bleeding, the agency said in a news release.

Coagadex, derived from human blood plasma, has been approved for people 12 years and older to control and prevent random bleeding episodes, and those stemming from menstruation or recent surgery.

The product was evaluated in clinical studies of 16 people with the rare [bleeding](#) disorder, which affects men and women equally. No safety concerns were identified in these studies, the FDA said.

Coagadex is manufactured by Bio Products Laboratory Ltd., based in the United Kingdom.

More information: Learn more about this approval from the [FDA](#).

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